IN THE SUPREME COURT OF MICHIGAN

NO. 124213

IN RE PETITION FOR AN ADMINISTRATIVE ORDER

****

REFERENCE MATERIAL SUBMITTED BY

THE COALITION FOR LITIGATION JUSTICE, INC., NATIONAL ASSOCIATION OF MANUFACTURERS, MICHIGAN MANUFACTURERS ASSOCIATION, CHAMBER OF COMMERCE OF THE UNITED STATES, MICHIGAN CHAMBER OF COMMERCE, MICHIGAN LUMBER AND BUILDING MATERIALS ASSOCIATION, NATIONAL ASSOCIATION OF WHOLESALER-DISTRIBUTORS, NATIONAL FEDERATION OF INDEPENDENT BUSINESS LEGAL FOUNDATION, AMERICAN TORT REFORM ASSOCIATION, AMERICAN INSURANCE ASSOCIATION, ALLIANCE OF AMERICAN INSURERS, NATIONAL ASSOCIATION OF INDEPENDENT INSURERS, MOTOR & EQUIPMENT MANUFACTURERS ASSOCIATION, AMERICAN CHEMISTRY COUNCIL, AMERICAN PETROLEUM INSTITUTE, INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION, AND WASHINGTON LEGAL FOUNDATION

IN SUPPORT OF PETITION TO ESTABLISH A COURT RULE OR ADMINISTRATIVE ORDER CREATING A STATEWIDE INACTIVE ASBESTOS DOCKETING SYSTEM

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VOLUME IV

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MEALEY'S LITIGATION REPORT

Asbestos

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Vol. 18, #10 June 18, 2003

Commentary

Understanding Asbestos-Related Medical Criteria

By
Dr. John E. Parker

[Editor's Note: Dr. John E. Parker, M.D., is a board certified pulmonologist and a B-reader who is currently on staff with the West Virginia Medical Center in Morgantown, West Virginia. Dr. Parker was a former medical officer, acting chief officer and chief officer with the National Institute for Occupational Safety and Health (NIOSH). At NIOSH, among other things, Dr. Parker was involved in overseeing and administering the tests for the B-reader certification program. The views expressed herein are the author's own. Responses to this column are welcome. Copyright 2003 by the author.]

Medical criteria for the treatment of asbestos claims are not new. Medical criteria have also been used by the courts and by parties settling asbestos claims for many years. Perhaps the most recent attempt to develop objective medical criteria for asbestos claims was the American Bar Association's adoption of its "ABA Standard for Non-Malignant Asbestos-Related Disease Claims" in February 2003. The ABA guidelines, which the ABA urged Congress to include as part of federal asbestos legislation, require that the filing of a civil action alleging personal injury for asbestos-related nonmalignant disease be accompanied by a detailed narrative medical report, signed by the diagnostic physician, demonstrating the following:

a. An occupational and asbestos exposure history and a detailed medical and smoking history;

b. Fifteen years elapsed time between the claimant's first exposure to asbestos and the time of diagnosis;

c. A quality chest x-ray, read by a NIOSH certified B-reader, demonstrating specific physical changes;

d. Lung or breathing impairment through properly administered pulmonary function tests; and

e. The physician's conclusion that the claimant's medical findings and impairment were not more probably the result of other causes revealed by the claimant's employment and medical history.[1]

The ABA guidelines do not appear to mandate any specific formula for the medical diagnosis of asbestos-related lung disease, but rather, spell out minimal requirements for compensation consideration. However, the ABA guidelines highlight the fact that there is no single test or medical tool that is available for either diagnosing a non-malignant asbestos-related disorder or measuring the extent of any impairment resulting from such a disorder. It is not enough if one of these factors, such as an x-ray, is merely consistent with exposure to asbestos. Instead, all of the different criteria identified in the guidelines — medical and exposure history, latency period, chest x-ray, pulmonary function test — must be considered together. The purpose of this article then, is to provide a primer on the most common types of non-malignant asbestos disorders and to explain the medical criteria used by physicians to evaluate the presence and severity of those disorders.

I. Nonmalignant Disorders And Asbestos Exposure

Asbestos exposure has been associated with certain malignant disorders, including mesothelioma (cancer of the lining of the lung) and other types of lung cancer. Asbestos exposure is also associated with certain non-malignant (or non-cancer) disorders. The most well known non-malignant chest disorders caused by exposure to asbestos involve the pleura of the lung and the lung itself.

The pleura of the lung consist of the thin linings or membranes surrounding both the lung and the inner surface of the chest wall. The lining adjacent to the chest wall is referred to as the parietal pleura and the lining adjacent to the lung is the visceral pleura. The two most common benign pleural abnormalities associated with asbestos are called pleural plaques and diffuse pleural thickening. Pleural plaques are typically localized, irregular thickenings adjacent to the parietal pleural surface on the chest wall while diffuse pleural thickening affects the visceral pleura surrounding the lung.

With regard to the lung itself, the most common disorder associated with asbestos exposure is lung fibrosis, referred to as asbestosis. An important function of the lung is to perform gas exchange between air and blood. This is accomplished through a series of conducting airways such as the trachea and bronchi, gas exchange structures called alveoli, and blood vessels or the pulmonary arteries, veins, and capillaries. The gas exchange region of the lung is also referred to as the pulmonary parenchyma. Asbestosis is a lung disorder characterized by fibrosis of the alveoli or injury to the pulmonary parenchyma caused by inhaled asbestos fibers. This fibrosis may cause a type of lung injury often referred to as interstitial lung disease. The phrases interstitial fibrosis or pulmonary fibrosis are often used interchangeably, and refer to scarring at the gas exchange region of the lung.

In describing these non-malignant disorders, a number of things are worth bearing in mind. First, the great percentage of people exposed to asbestos (anyone living in a city today has been exposed to asbestos) will not suffer from any of these disorders. Second, pleural plaques may occur without asbestosis and asbestosis may be present without plaques; these two disorders also may both occur together in one individual. Third, pleural plaques, pleural thickening and interstitial lung disease have causes other than asbestos exposure and in cases involving asbestos, typically can be seen on both lungs (the disorders are "bilateral"). Finally, the severity or extent of pleural disorders and asbestosis likely relates to the intensity and duration of exposure to asbestos fibers (significant exposure to asbestos over time is required for these nonmalignant disorders), the type of asbestos, and the exposure latency or lapsed time since initial exposure.

II. Medical Criteria Are Well-Known In The Medical Community

Two questions are at the heart of asbestos-related medical criteria — how much evidence is necessary to firmly establish a diagnosis of a disorder and how can one determine if that disease is causing impairment. The medical community has addressed these issues for years.

For example, the American Thoracic Society ("ATS") published widely accepted criteria for the diagnosis of asbestosis as early as 1986.[2] (The ATS was formed as a division of the American Lung Association back in 1905. It is an independent, international, educational and scientific society which focuses on respiratory and critical care medicine. The society today has about 13,500 members who are mainly clinical physicians and scientists that prevent or treat respiratory illnesses.) The ATS guidelines for the diagnosis of asbestosis require an adequate history of exposure to airborne asbestos fibers, an appropriate latency period after fiber exposure to disease diagnosis, an abnormal chest x-ray with widespread fibrosis in the gas exchange region of the lung, and restrictive lung physiology.

The ATS requires a restrictive lung physiology because impairment from asbestosis is generally regarded as a restrictive disease. A restrictive disease results in the lungs not being able to accommodate sufficient air. The lungs diminish in size and restrict breathing. To illustrate, a person would have chest restriction if he or she were forced to breathe with a tight belt around the chest. By contrast, smoking related diseases such as emphysema or chronic bronchitis, as well as asthma, are obstructive diseases. Airway obstruction is a term that is used to define the condition where the lungs are not reduced in size as with restriction, but rather the airways do not allow the inhaled air to be rapidly or fully exhaled. There is obstruction to the emptying of air trapped in the lungs.

Although the diagnosis of asbestosis can be made with even more certainty if lung tissue from biopsy or autopsy is available, the majority of clinical evaluations for asbestos-related fibrosis of the lung do not include tissue analysis. Instead, the diagnosis of asbestosis is typically based on the exposure history, chest x-ray, lung function testing, and the absence of illnesses that might mimic asbestosis. One of these tools, in and of itself, does not permit a diagnosis of non-malignant disease, which is why the ATS guidelines look at all of these criteria. The ATS guidelines remain as the guiding principles to establish a clinical diagnosis of asbestosis.

Demonstrating the presence of impairment also is not a new concept for the medical community. The American Medical Association (AMA) has published serial editions of *Guides to the Evaluation of Permanent Impairment (Guides)* addressing human impairment induced by disease. The *AMA Guides* have a chapter devoted to assessment of the respiratory system for impairment and define impairment as "the loss, loss of use, or derangement of any body part, organ system, or organ function."[3] Statutes or regulations in at least 40 states have adopted the *AMA Guides*. In addition to the *AMA Guides*, the Social Security Administration also publishes and updates editions of *Disability Evaluations under Social Security* that address issues concerning asbestos-related impairment.[4]

III. Medical Criteria Used For Non-Malignant Disease

The medical evaluation of individuals with potential non-malignant lung diseases from asbestos exposure typically requires a respiratory history, physical examination, chest x-rays and lung function testing. Each of these tasks has limitations.

- The **respiratory history** includes inquiry about pulmonary symptoms, typically shortness of breath or cough. The exposure history to airborne contaminants including asbestos is also needed. The physician should also take a detailed medical and smoking history that includes a thorough review of past medical problems and their most probable cause. Because breathing difficulties and cough are symptoms of many lung disorders, are more prevalent among older patients and, of course, are not specific to asbestos disease, a complete and detailed respiratory history is critical to a proper diagnosis.

- The **physical examination** focuses primarily on the presence or absence of inspiratory "crackles" during the chest exam and/or clubbing of the fingers. Crackles refer to the presence of fluid or fibrosis in the lungs that cause crackling sounds audible with a stethoscope. Clubbing refers to a characteristic enlargement and sponginess of the fingertips, often involving the tips of the toes as well. These findings may be seen in asbestosis but, again, they are not specific to asbestos disease and are present in various other diseases. Indeed, when associated with asbestos, they are typically only seen in the more severe cases of asbestos-related disease.

- The **chest x-ray** is another valuable tool to assess the presence of abnormalities of the pleura or lung. A standardized method for reading x-rays has been published by the International Labor Office (ILO) and is often used to recognize and classify dust diseases of the lung.[5] The ILO system was originally established to improve disease detection and achieve consistency in x-ray film interpretation for epidemiological investigations.

Despite efforts toward standardization in chest x-ray interpretation through the use of the ILO system, however, there remain inconsistencies among different x-ray readers (or even inconsistencies by the same reader at different times) as to whether an x-ray shows the presence or absence of abnormalities.[6] In the United States, the National Institute for Occupational Safety and Health (NIOSH) administers a quality assurance program for the training, testing and certification of physicians, known as the "B reader" program, to help provide greater consistency among x-ray readers.[7]

The ILO Classification System consists of (1) written guidelines, (2) standard or reference chest x-rays that can be used as guides, and (3) a specific form for recording findings and observations of each chest x-ray that is reviewed. The system first requires the chest x-ray reader to rate the film quality and then record the presence or absence of any "shadows" or "opacities" on the chest x-ray that are consistent with asbestos exposure.

Next, the chest x-ray reader must identify the zone or zones in the lung (upper, middle and lower) where the abnormalities have been found and record a size and shape of the abnormal shadows. The size and shape are identified by six letter designations — p, q, r, and s, t, u. The letter designations most commonly associated with asbestos induced "shadows" are of the "s" and "t" type, and these correspond with small irregular or linear shadows on the film and usually are found in the lower lung zones. The shape of the abnormalities and the zone of the lung where they are found are important factors in determining whether there is any relationship to asbestos. In contrast to asbestosis, the classic radiological findings for simple silicosis involve rounded opacities with "shadows" of the "p," "q" or "r" type that generally are located in the upper lung zones.

The chest x-ray reader also classifies these small opacities or abnormal shadows utilizing a scale that uses the numbers 0, 1, 2, and 3 to represent normal, mild, moderate, and severe abnormalities respectively. The chest x-ray reader classifies the x-ray by assigning two numbers. (When classifying a chest x-ray, the x-ray is compared to the standard or reference x-rays which have predetermined classifications.) The first number is the reader's primary classification of the film. The second number is the other classification the reader seriously considered. A classification of 1/0 means the reader's final determination was the category 1 classification (mild), but seriously considered category 0, or normal. Thus, 0/-, 0/0, or 0/1 represent three "shades" of normal. On the other end of the spectrum, 3/2, 3/3, or 3/+ are the sub-categories of severe abnormality.

The ILO system also prescribes another method for describing pleural abnormalities. This method includes the review of the radiograph and the classification of abnormalities by the use of letters A, B, or C for increasing thicknesses or "widths." A numerical description using the numbers 0, 1, 2, or 3 is coupled with the thickness/width classifications and together they are used to describe the length or extent of chest wall plaques. For example, a B2 plaque means it has a thickness or width grade of B which is greater than five millimeters but less than ten millimeters and an extent grade 2, which is a total vertical height of greater than ¼ but less than ½ of the height of the lateral chest wall.

Although chest x-rays have many advantages, they are an imperfect tool for diagnosing asbestosis and pleural abnormalities. The radiographic findings for asbestosis are not specific to asbestos.[8] The small abnormalities on the chest x-ray associated with asbestosis often are no different than the x-ray "shadows" caused by other types of fibrosis. Further, the chest x-ray is a non-invasive test that allows for good, but far from precise, visualization of normal and abnormal anatomical structures. Chest x-rays are held in high public esteem, likely due to their role in tuberculosis screening in the past century. But the presence of irregular or linear shadows detected by chest x-ray alone does not currently permit a diagnosis of non-malignant asbestos-related disease, nor does it establish functional impairment from asbestos exposure.

- **Lung function testing** is necessary for evaluating the severity of non-malignant asbestos-related disease. Lung function testing primarily includes spirometry, lung volumes, diffusing capacity, and cardiopulmonary exercise testing. The performance and interpretation of these tests are well standardized by published statements of the American Thoracic

Society.[9] Each involves powerful and well-validated tests that are important in the diagnosis and management of lung disease.

- Spirometry is a routine medical test that requires the subject to take the deepest breath possible and then to rapidly and completely exhale the air from the lungs. This full complete "deep breath" followed by forcibly "blowing out" all of the air allows the measurement of the total air exhaled called the forced vital capacity or FVC. A second measurement performed during this forced breathing maneuver is the 1-second forced expiratory volume or FEV1. The FEV1 measures the quantity of air forcefully exhaled in one second.

An important tool is the Forced Expiratory Volume 1/Forced Vital Capacity (FEV1/FVC) ratio: the ratio of the FEV1 divided by the FVC. It measures how fast the air comes out in the first second of exhalation of the test (FEV1) compared to how much air is forcefully exhaled out totally (FVC). The ratio for a patient can then be compared to "normal" or "expected" values.

Normal or expected values for FVC and FEV1 are published as reference values and were developed by the study of normal or healthy populations. The major determinants of FVC and FEV1 are age, gender, height, and ethnicity. Reference values decrease slowly for increasing height and age. To determine whether FVC or FEV1 test results are abnormal, an individual's result is compared with the published normal or predicted reference values.[10] For any given individual, there is a range of FVC or FEV1 that is considered normal. This range is usually identified by a statistical test to determine what is called the lower limit of normal. To determine the lower limit of normal, the published predicted or reference value is adjusted by a statistical "confidence interval." One statistically acceptable approach for establishing lower limits of normal for FVC, FEV1 or FEV1/FVC is to define the lowest 5% of the reference populations as below the lower limit of normal. The *ABA Guides* utilize lower limits of normal as the standard for identifying asbestos-related impairment.

In the past, some have used a different standard other than the lower limit of normal to define what is considered normal. Such a standard often involves using a fixed percent of the predicted value (such as using less than 80% of predicted) as an abnormal cutoff. This standard has no statistical basis in adults according to the ATS. The use of a fixed percent of the predicted value as abnormal is also unreliable because it results in shorter, older subjects being more readily classified as "abnormal" and some younger, taller subjects being misclassified as "normal."

Spirometry is an essential component of an asbestos-related disease diagnosis and the assessment of potential impairment, and the spirometry exam is easily performed and relatively inexpensive. The stiff and scarred lung in severe cases of asbestosis induces a typical restrictive lung disease, and reduces the forced vital capacity. The hallmark of restrictive lung disease is a reduced FVC with preservation of the ratio between the FEV1 and FVC. The ratio of FEV1 to FVC is normally around 70 percent or greater (or above the actual lower limit of normal for FEV1/FVC). The findings in obstructive diseases such as in emphysema are an FEV1 to FVC ratio of less than around 70 percent (or below the actual lower limit of normal for FEV1/FVC).

- A second lung function test is the measurement of lung volumes; either using a body box called plethysmography, or timed gas dilution. Lung volume testing measures Total Lung Capacity or TLC, which refers to how much air is in the lungs after a maximum inhalation. The TLC is considered the gold standard for identifying lung restriction and is more precise than spirometry.[11] The TLC may be used to determine whether there is a restrictive impairment, such as seen in asbestosis. A restrictive impairment reduces the total capacity of the lung, while obstructive lung diseases usually do not reduce the TLC and may indeed frequently induce an increased TLC. Thus, a low TLC is more consistent with an asbestos-related disorder.

- A third lung function test that may be helpful is the diffusing capacity for carbon monoxide or the DLCO. Diffusing capacity measures the ability of the lungs to transfer gas from inhaled air to the red blood cells in the pulmonary capillaries. The DLCO is relatively easy to perform. The test requires a quick deep inhalation of 0.3 percent carbon monoxide followed by a ten-second breathhold by the subject and then a rapid exhalation. It is worth noting, however, that this test does not separate obstructive from restrictive lung diseases; both emphysema and interstitial lung diseases such as asbestosis can reduce the DLCO.

Finally, cardiopulmonary exercise testing can be performed as an adjunctive means of assessing disease severity. When properly performed and interpreted it can help to differentiate pulmonary impairment from cardiac impairment or the effects of physical deconditioning. Exercise studies are expensive and used sparingly in impairment evaluations and often only when it is necessary to clarify the nature of impairment. These studies are not routinely used when other pulmonary function studies are normal and also are not generally important when spirometry, DLCO, or lung volumes already indicate severe impairment.

Summary

Medical criteria are available both to perform diagnostic assessment of asbestos exposed individuals and to measure the extent of impairment for non-malignant asbestos diseases. The challenge will be to create acceptable objective methods for separating diseased from non-diseased individuals, and to separate impaired from unimpaired individuals. Any attempt to come up with widely acceptable criteria, of course, will require an understanding of the limitations posed by the particular medical tools available and the recognition that several factors — occupational history, latency period, chest x-rays, and lung function tests — need to be considered.

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Testimony

United States Senate Committee on the Judiciary

Solving the Asbestos Litigation Crisis: S. 1125, the Fairness in Asbestos Injury Resolution Act of 2003

June 4, 2003

Dr. James D. Crapo

Department of S/M Pulmonary Sciences/Critical Care Medicine , National Jewish Medical Research Center

WRITTEN STATEMENT OF DR. JAMES D. CRAPO, PROFESSOR OF MEDICINE, NATIONAL JEWISH CENTER AND UNIVERISTY OF COLORADO HEALTH SCIENCES CENTER, BEFORE THE SENATE COMMITTEE ON THE JUDICIARY CONCERNING S. 1125, THE FAIRNESS IN ASBESTOS INJURY RESOLUTION ACT OF 2003

JUNE 4, 2003

Mr. Chairman, my name is Dr. James Crapo. I am a pulmonary specialist in Denver, Colorado. I appreciate your inviting me here today to testify with respect to S. 1125, the "Fairness in Asbestos Injury Resolution Act of 2003." I shall discuss, in particular, the medical provisions of the bill.

My remarks fall into three parts. First, I will explain my background, and why I am here to testify. Second, I will briefly describe the health effects of asbestos exposure. Third, I will summarize the medical provisions of the proposed statute and explain my conclusion that those provisions are generally reasonable in the context of an overall compromise among conflicting viewpoints. I will also note, however, certain areas in which I believe the medical provisions of the bill may be unduly lax, resulting in the possible payment of awards to people who are not sick as a result of any asbestos-related illness.

I am being compensated for my time at my usual consulting rates by the Asbestos Alliance and the Asbestos Study Group, both of which support the bill before the committee.

My Background

I am currently Professor and Chairman of the Department of Medicine at the National Jewish Center and University of Colorado Health Sciences Center. I graduated from the University of Rochester School of Medicine in June of 1971 and subsequently trained at Harbor General Hospital in Torrance, California, the National Institute of Environmental Health Sciences, and Duke University. Before coming to the National Jewish Center I served for more than 20 years on the medical faculty of Duke University, and for 17 of those years I was the Chief of Duke's Division of Pulmonary and Critical Care Medicine. I am also the member of numerous professional societies. I served as the President of the American Thoracic Society in 1992 and I am currently President Elect of the Fleischner Society, a leading international society of selected specialists in radiology and pulmonary medicine. I am Board Certified in Internal Medicine and Pulmonary Diseases.

In my current position I care for patients. I teach medical students and direct the PhD Program for Graduate Health Care Professionals at the University of Colorado Health Sciences Center. I also conduct research and have published a multitude of peer-reviewed articles on the respiratory system. I am the co-author of several leading textbooks on pulmonary medicine. I have also served from time to time as an expert witness in asbestos litigation and have had the opportunity to observe that litigation first hand.

The Health Effects of Asbestos

All of us are exposed to asbestos from the environment and consequently have asbestos in our lungs. This "background" level of exposure does not cause any asbestos-related disease. Those diseases normally require substantial occupational exposures or the equivalent. Moreover, the amount of asbestos to which people have been exposed varies greatly by occupation and work setting. Due to federal regulation of asbestos that began in the early 1970s, current occupational exposure levels are a tiny fraction of those that existed in the 1940s and 1950s. All of the asbestos-related diseases are considered dose dependent, and the pre-1973 exposures to asbestos that resulted in severe asbestosis and lung cancer are not present today.

We know that substantial exposure is required to produce asbestos-related diseases for several reasons. First, a 1997 study of Canadian miners and millers who were exposed to substantial amounts of asbestosis – up to 300 particles/cu. ft.-year – showed minimal increases in asbestos-related diseases. Second, a 1998 study of women who lived near mining and milling operations showed no increased incidence of lung cancer, although there were several excess mesotheliomas. These women received primarily take-home and environmental exposures, averaging of 25 fibers/cc-years – a level normally seen only occupationally. Third, ambient levels of asbestos very greatly across the United States with urban environments such as New York City and San Francisco having levels from 0.003 to 0.03 fibers/cc. These ambient levels of asbestos can lead to lifetime exposure in the range of 2-3 fiber/cc years and yet have not been shown to be associated with an increased incidence of asbestos-related diseases. Finally, my laboratory has undertaken an extensive evaluation of lung injury responses in rats after an acute exposure to asbestos dust. Animals exposed acutely to 2.5 fibers/cc-year showed only small local areas of inflammation in the short term. After one year these animals were able to repair the initial inflammation and had normal lungs. There was no long term fibrosis and no progression. The important point here is that, while asbestos can be responsible for very serious and even fatal diseases, that is not true of low level or incidental, background exposures. The lungs are good at defending themselves, and it takes a significant exposure to produce most asbestos-related conditions.

The primary asbestos-related conditions found in humans include 1) pleural changes or reactions, 2) pulmonary fibrosis (which, when caused by asbestos, is called asbestosis), 3) lung cancer, and 4) mesothelioma. It is sometimes asserted, based on early work done by Selikoff, that several other kinds of cancer – including gastro-intestinal cancers – are associated with asbestos exposure. However, the early results have not been confirmed in subsequent studies, and most medical experts at present believe that there is no persuasive evidence of a linkage between asbestos and any cancers other than lung cancer and mesothelioma.

None of these asbestos-related conditions is due exclusively to asbestos, and if asbestos could somehow be eliminated from the planet, all of those conditions would continue to exist. This is true even of mesothelioma. While asbestos is today the only clearly identified cause of mesothelioma, it is generally accepted that a substantial proportion of all mesothelioma cases are "idiopathic" – i.e., they have some as-yet unidentified cause other than asbestos exposure. A major task of the medical eligibility requirements in the bill is to determine when a given medical condition is due to asbestos exposure and when it is due to an alternative cause.

Pleural Changes. The pleura is a membrane that surrounds the lungs. It is not itself a part of the lung tissue. Asbestos can cause changes in pleura, such as pleural plaques or pleural thickening. These pleural changes are not the same as asbestosis and do not increase the risk of developing asbestosis. Unless they are very extensive, pleural changes do not affect lung function, and there is no evidence that they increase the risk of an asbestos-related cancer. Pleural plaques may be a marker of asbestos exposure, but they can also result from other causes such as trauma or inflammation. Similarly, pleural thickening has a number of causes other than asbestos.

Asbestosis. Clinical asbestosis is a kind of pulmonary fibrosis -- a diffuse, bilateral scarring of lung tissue which in the case of asbestosis is due to asbestos fibers in the lungs. This type of lung fibrosis can also occur as a result of a large number of other lung diseases, and a chest x-ray determination of lung fibrosis is not specific for asbestosis. The scarring or fibrosis of the lung can lead to a reduction in total lung capacity, which ultimately can produce severe breathing impairment and even death. In many cases, however, asbestosis has few or no symptoms. Moreover, while asbestosis is often considered a "progressive" disease – that is, it can get worse even after exposure to asbestos stops – with the relative small exposures that are typical of people who have asbestosis today, the disease progresses very slowly, if at all. Most people who have asymptomatic asbestosis today never will develop any breathing impairment as a result of their disease.

There is an exposure threshold below which clinical asbestosis will not occur. Individual susceptibility is also an important factor. Even among individuals who are exposed to levels above the threshold necessary to develop disease, some may develop asbestosis and others may not.

The threshold for the development of clinically detectable asbestosis is a cumulative dose of approximately 25 fibers/cc-years. Reaching this threshold of exposure does not necessarily indicate that clinical asbestosis will occur. At a cumulative dose of approximately 75 to 100 fibers/cc-years, the risk of contracting clinical asbestos is on the order of 1 percent.

Lung Cancer. The development of lung cancer can be associated with asbestos. It is, however, impossible to distinguish clinically between a lung cancer caused by asbestos and one caused by something else. Physicians must therefore rely on statistical evidence. There is a debate in the medical community as to whether lung cancer can be attributed to exposure to asbestos in the absence of clinically significant asbestosis. I personally believe that the answer to that question is no. Most of my colleagues agree with that view or believe that lung cancer cannot be attributed to asbestos unless there is at least enough exposure to have caused asbestosis. Thus the exposure threshold for causation of asbestosis would also apply to the causation of lung cancer. There is a small minority viewpoint, however, in favor of the "single-fiber" theory, which holds that any exposure to asbestos is sufficient to cause a lung cancer.

There is a separate debate about the interaction between asbestos exposure and smoking and whether the scientific evidence supports an association between asbestos and lung cancer in the absence of smoking. I believe that the synergistic relationship with smoking described in the literature is most appropriately a relationship of clinically significant asbestosis and cigarette smoking. The risk of lung cancer among smokers is influenced by several factors such as, for example, the age at which a person starts to smoke, the number of cigarettes smoked per day, the number of years smoked, and the depth of inhalation of the smoke. Exposure to side stream smoke or second hand has also been shown to increase the risk of lung cancer. There is no debate that the increased smoking cessation will reduce the risk of lung cancer, however. This benefit from smoking cessation is markedly reduced in those who have smoked heavily. Smoking 40-50 pack years is associated with an elevated risk of lung cancer that persists for decades after smoking cessation. Lung-cancer risk of non-smokers exposed to asbestos, if any, is far less than the risk of smokers.

Mesothelioma. Mesothelioma is a relatively rare tumor of the pleura or peritoneum. Although asbestos exposure has been associated with mesothelioma, there are a substantial number of cases a year of mesothelioma where these is no indication that the individual was ever exposed to elevated levels of asbestos. However, more than half the cases of mesothelioma in the United States can be shown to be caused by exposure to amphibole types of asbestos. The most commonly used type of asbestos in the United States, chrysotile, has a much lower propensity to cause mesothelioma in comparison to the amphibole forms of asbestos. Although most mesotheliomas are caused by exposures to high cumulative doses of amphiboles, these tumors can occur after relatively low exposures. There is a threshold for exposure to asbestos below which there is no risk for development of mesothelioma. For chrysotile, exposure levels at least equivalent to that required to cause asbestosis are required to contribute to the causation of mesothelioma.

The Medical Criteria of S. 1125

Having discussed the major health effects of asbestos, I turn now to the medical eligibility requirements of S. 1125. At the outset, it is important to note two general requirements. First, every claim upon the Fund created by the bill must be supported by a medical diagnosis that meets the requirements of Section 122. The provisions of Section 122 are comprehensive. They speak to the qualifications of the physician, the requirement of an in-person exam by a treating physician who has done a review of the patient's medical, smoking, work and exposure history, the technical sufficiency of x-rays, pulmonary function tests, and other laboratory results, and the usual medical requirement that the physician exclude other more likely causes of the claimant's condition in determining whether that condition is due to asbestos exposure. As a practicing physician, I think those diagnostic requirements are completely appropriate. In particular, the requirement that the physician exclude more likely causes of the claimant's condition is extremely important. As I indicated above, all of the health effects of asbestos are caused by other things as well, and a diagnosis cannot be well founded if it does not exclude these other alternative causes.

The second general requirement is latency – i.e., the time that has elapsed from first exposure to the date of diagnosis. While Section 123 of the bill would give the asbestos court flexibility in setting different latency periods for different diseases, at the outset the bill establishes a 10-year latency requirement across the board. This period of time is much lower than the average latency of many asbestos-related conditions, particularly under conditions of low asbestos exposures. The latency period for mesothelioma, for example, can be 40 years. While a 10-year latency requirement may be somewhat permissive, it is not inappropriate in the context of a compromise for settling all asbestos cases outside the court system.

The bill's medical criteria are divided into eight levels. With one trivial exception, Levels I through IV address non-cancerous conditions, while Levels V through VIII deal with cancers.

Non-Malignant Conditions. Levels I and II define asymptomatic, non-cancerous conditions. Level I requires (a) a diagnosis of an "asbestos-related non-malignant disease," which must be based on x-ray evidence of asbestosis (i.e., an ILO reading of 1/0) or pleural changes, and (b) a brief (6-month period) of occupational exposure to asbestos prior to December 31, 1982. Level II requires a similar diagnosis but has a more stringent exposure requirement. A claimant can qualify for either of these levels without showing any breathing impairment.

The bill provides medical monitoring for people who fall within these two levels. I believe that that is appropriate. Medical monitoring may provide some reassurance, and it will allow people with potentially abnormal x-rays to discover promptly when they may qualify for an award. Because of the large number of people who could qualify for Levels I and II, an award of compensation to people in these categories could result in a diversion of funds away from people who are genuinely sick to people who have basically asymptomatic conditions. Moreover, the definition of bilateral asbestos-related nonmalignant disease is general and could apply to a large number of diseases with causes unrelated to asbestos.

Level III is the first category that provides for a compensatory award. This level has four basic requirements. The first is a diagnosis of asbestosis or pleural changes. The asbestosis diagnosis must be based on either an ILO reading of 1/0 or pathology, while the diagnosis of pleural changes must be based x-ray evidence of pleural thickening or pleural plaques of a substantial size – i.e, those that are at least a B2 on the ILO scale. Second, the claimant must show breathing impairment of a kind that is consistent with asbestos-related disease. Third, the claimant must show 6 months exposure to asbestos in 1982 or earlier and "significant occupational exposure to asbestos." Fourth, the claimant must present medical documentation that asbestos-exposure is a contributory cause of his condition.

The medical criteria for Level III seem appropriate in the context of an overall compromise. I do, however, have two reservations. The first has to do with the measure of impairment. It is generally accepted that the cut-off between normal and abnormal on such pulmonary function tests as "total lung capacity" ("TLC") or "forced vital capacity" ("FVC") should be set at the statistical 5th percentile rather than a rule-of-thumb number such as 80%, which does not take into consideration such factors as height or age. More importantly, one of the prescribed tests for impairment, FVC, will allow many people to qualify for an award even though their breathing impairment is due to emphysema or other obstructive diseases caused primarily by smoking. The reason for this is that the claimant can still qualify for an award with an FEV1/FVC ratio of as low as 65%, even though a ratio under 70% or 75% is indicative of obstructive (non-asbestos) lung disease.

My second reservation has to do with the definition of "significant occupational exposure" in Section 124(a)(8) of the bill. Generally, that definition requires employment for 5 years in an industry or occupation in which the claimant (a) handled raw asbestos fibers on a regular basis, (b) fabricated asbestos products in such a way that the claimant was regularly exposed to raw asbestos fibers, (c) altered, repaired, or worked with asbestos products in a way that the claimant was regularly exposed to asbestos fibers, or (d) worked in close proximity to workers covered by the above provisions. If applied strictly, this definition would be a reasonable proxy for the minimum levels of exposure that are necessary to cause asbestosis and lung cancers. It is conceivable, however, that clause (c) would be read broadly to include people who work with encapsulated asbestos-containing products under circumstances in which very few asbestos fibers escape into the air. To treat exposures of this kind as equivalent to exposures received working with raw asbestos fibers would not make any sense. This is important because, with the passage of time, fewer and fewer claimants will qualify on the basis of their work with raw fibers (because regulations will have limited such exposures) and more will seek to qualify on the basis of work with and around finished products, in low-dose environments. Such a shift would make significant occupational exposure mean less and less as time goes by. This problem is exacerbated by the language in clause (d), which would allow those who worked in proximity to workers satisfying the requirements of clause (c) also to qualify, even though their exposure is even more attenuated.

The final non-malignant category, Level IV, provides for cases of severe asbestosis. To qualify for this level, a claimant must demonstrate asbestosis (and not mere pleural changes) through either a definitive x-ray of 2/1 or pathology and must present pulmonary function tests showing severe impairment. The claimant must also meet the same exposure and medical documentation requirements as claimants for Level III.

My reservations about Level III – the danger that many people with obstructive pulmonary diseases rather than asbestos-related disease will obtain awards and concern about the interpretation of significant occupational exposure – apply in principle to Level IV. However, the requirement of a 2/1 chest x-ray, which may be strongly indicative of asbestosis, significantly limits the extent of the problem as a practical matter. Generally, therefore, I believe Level IV is an appropriate category.

Cancers. Cancer claims are divided into four levels. Level V consists of "other cancer" – i.e., primary cancers of the larynx, the esophagus, the pharynx, or the stomach. Level V does not include colo-rectal cancer, which is one of the most widespread cancers in the United States. Claimants may qualify for an award under Level V by showing (in addition to the requisite cancer) evidence of an underlying bilateral asbestos-related disease (generally, a 1/0 chest x-ray or x-ray evidence of pleural plaques), exposure (6 months exposure in 1982 or earlier and significant occupational exposure), and medical documentation of a causal relationship.

As I explained above, the decided weight of the evidence is that these cancers are not caused by asbestos at all. However, since there is a minority viewpoint in the medical community on this point, including these cancers in a compensable category may make sense in the context of an overall compromise. As part of that compromise, however, it also makes sense to exclude colo-rectal cancers. According to the National Cancer Institute, there are 147,500 colo-rectal cancers each year. To allow recovery based on nothing more than plaques and the requisite exposure could expose the Trust to considerable, unpredictable liabilities in future years. This would be ironic, since asbestos litigation as it is today involves few "other cancer" cases, presumably because of the difficulties of proof. There is a danger that the medical criteria in the bill would open the door to many more claims of this kind than are currently seen.

Levels VI and VII both deal with Lung Cancer. The relationship between the two is somewhat complex. At the outset, only non-smokers – defined either as people who have never smoked or as people who have not smoked within the 12 years immediately prior to the diagnosis – can use Level VI, `because the scheduled value for smokers under Level VI is $0. This means that, as a practical matter, smokers must apply under Level VII.

In effect, Level VI allows non-smokers to obtain a limited award ($50,000) on a showing that they have a primary lung cancer, six months exposure to asbestos in 1982 or earlier, and documentation of causation. In my view, there is no adequate justification for Level VI. As noted above, I doubt that asbestos is associated with an increased risk of lung cancer in non-smokers, but in any event there is no basis whatever for attributing a lung cancer to asbestos on the basis of 6 months exposure unless that exposure was truly massive. Most, if not all, of the people who qualify for an award under Level VI will not in fact have an asbestos-related lung cancer.

To be sure, this problem is limited, because most asbestos workers smoked. Many, however, also quit smoking in recent years, and thus may meet the bill's definition of a non-smoker – someone who hasn't smoked in the 12 years before the diagnosis. Moreover, it is difficult to establish in a non-adversarial administrative proceeding whether a person quit smoking at the requisite time or not. Consequently, I believe that Level VI as written poses an unjustified threat to the financial integrity of the Fund.

Level VII is, and should be, the principal Lung Cancer category. It requires a claimant to demonstrate (a) a primary lung cancer, (b) evidence of an asbestos-related non-malignant disease (asbestosis as shown by a 1/0 ILO reading or pleural plaques), (c) 6-months occupational exposure prior to December 31, 1982 and significant occupational exposure, and (d) supporting documentation of causation. I believe that these criteria are generally appropriate as part of an overall compromise. I do have two reservations, however. One is my concern that "significant occupational exposure" will be interpreted too loosely, leading to a large number of unjustified claims in future years. The second is that the provision requiring an underlying asbestos-related non-malignant disease is too permissive in that it allows a claimant to satisfy this requirement with pleural plaques alone. While asbestosis is a risk-factor for lung cancer, pleural plaques are not. Moreover, while pleural plaques confirm that the claimant was exposed to asbestos, such confirmation adds nothing important to the exposure requirements. In my opinion, it would make more sense to require, as a condition for a lung-cancer award, clinically significant asbestosis.

Finally, Level VIII addresses mesothelioma claims. It requires only a mesothelioma diagnosis plus evidence of some exposure to asbestos prior to December 31, 1982. Although the language is not clear, I assume that this provision does not permit an award based solely on the background exposure that everyone has to asbestos fibers in the environment. The bill should be interpreted as requiring a discrete and identifiable exposure that goes significantly beyond background.

Conclusion

My conclusion is that S. 1125 is a sensible compromise designed to provide a reasonable alternative to asbestos litigation in the courts. It is unlikely that any substantial number of people genuinely sick as a result of exposure to asbestos will be unable to recover from the Fund. Moreover, the Fund will direct most of its resources to the appropriate categories: severe asbestosis (Level IV), lung cancer (Level VII), and mesothelioma (Level VIII). As one would expect of a compromise, however, there are provisions in the bill that appear to me to be unduly permissive and that might be tightened in order to protect the financial integrity of the fund – and thus the ability of deserving asbestos victims to obtain awards in years to come. Level VI is a good example of an unwarrantedly liberal eligibility requirement.

In closing, I would like to commend you, Mr. Chairman, Senator Leahy, and this committee for the work you are is doing to find a better way to compensate asbestos victims. I have witnessed the operation of the court system for many years. It would be difficult to imagine a more arbitrary and wasteful way to compensate people with asbestos-related diseases. Substituting a sensibly designed, streamlined, inexpensive, no-fault system would benefit everyone. In my view, S. 1125 is an excellent first step.

3

American Medical Association
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Guides *to the* Evaluation *of* Permanent Impairment

Fifth Edition

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Chapter 1

Philosophy, Purpose, and Appropriate Use of the *Guides*

1.1 History

1.2 Impairment, Disability, and Handicap

1.3 The Organ System and Whole Body Approach to Impairment

1.4 Philosophy and Use of the Combined Values Chart

1.5 Incorporating Science with Clinical Judgment

1.6 Causation, Apportionment Analysis, and Aggravation

1.7 Use of the *Guides*

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1.9 Employability Determinations

1.10 Railroad and Maritime Workers

1.11 The Physician's Role Based on the Americans with Disabilities Act (ADA)

1.12 Summary

1.1 History

The *Guides* was first published in book form in 1971 in response to a public need for a standardized, objective approach to evaluating medical impairments. Sections of the first edition of the *Guides* were originally published in the *Journal of the American Medical Association*, beginning in 1958 and continuing until August 1970.[1] Since then, the *Guides* has undergone four revisions, culminating in the current, fifth edition. The purpose of this fifth edition of the *Guides* is to update the diagnostic criteria and evaluation process used in impairment assessment, incorporating available scientific evidence and prevailing medical opinion. Chapter authors were encouraged to use the latest scientific evidence from their specialty and, where evidence was lacking, develop a consensus view. This chapter was revised from the earlier edition in response to specific requests from user groups concerning the definitions, appropriate use, and scope of application of the *Guides*.

The fifth edition includes most of the common conditions, excluding unusual cases that require individual consideration. Since this edition encompasses the most current criteria and procedures for impairment assessment, it is strongly recommended that physicians use this latest edition, the fifth edition, when rating impairment.

1.2 Impairment, Disability, and Handicap

1.2a Impairment

The *Guides* continues to define impairment as "a loss, loss of use, or derangement of any body part, organ system, or organ function."[1] This definition of impairment is retained in this edition. A medical impairment can develop from an illness or injury. An impairment is considered permanent when it has reached maximal medical improvement (MMI), meaning it is well stabilized and unlikely to change substantially in the next year with or without medical treatment. The term *impairment* in the *Guides* refers to permanent impairment, which is the focus of the *Guides*.

An impairment can be manifested objectively, for example, by a fracture, and/or subjectively, through fatigue and pain.[3] Although the *Guides* emphasizes objective assessment, subjective symptoms are included within the diagnostic criteria. According to the *Guides*, determining whether an injury or illness results in a permanent impairment requires a medical assessment performed by a physician. An impairment may lead to functional limitations or the inability to perform activities of daily living.

Table 1-1, adapted from a report by the AMA Council on Scientific Affairs, lists various definitions of impairment and disability used by four main authorities: the AMA *Guides*, the World Health Organization, the Social Security Administration, and a state workers' compensation statute.[4] Although a nationally accepted definition for impairment does not exist, the general concept of impairment is similar in the definitions of most organizations. Several terms used in the AMA definition, and their application throughout the *Guides*, will be discussed in this chapter and Chapter 2.

Loss, loss of use, or derangement implies a change from a normal or "preexisting" state. *Normal* is a range or zone representing healthy functioning and varies with age, gender, and other factors such as environmental conditions. For example, normal heart rate varies between a child and adult and according to whether the person is at rest or exercising. Multiple factors need to be considered when assessing whether a specific or overall function is normal. A normal value can be defined from an individual or population perspective.

When evaluating an individual, a physician has two options: consider the individual's healthy preinjury or preillness state or the condition of the unaffected side as "normal" for the individual if this is known, or compare that individual to a normal value defined by population averages of healthy people. The *Guides* uses both approaches. Accepted population values for conditions such as extremity range-of-motion or lung function are listed in the *Guides*; it is recommended that the physician use those values as detailed in the *Guides* when applicable. In other circumstances, for instance, where population values are not available, the physician should use clinical judgment regarding normal structure and function and estimate what is normal for the individual based on the physician's knowledge or estimate of the individual's preinjury or preillness condition.

Chapter 5

The Respiratory System

5.1 Principles of Assessment

5.2 Symptoms Associated With Respiratory Disease

5.3 Tobacco Use and Environmental Exposure Associated With Respiratory Disease

5.4 Examinations, Clinical Studies, and Other Tests for Evaluating Respiratory Disease

5.5 Asthma

5.6 Obstructive Sleep Apnea

5.7 Hypersensitivity Pneumonitis

5.8 Pneumoconiosis

5.9 Lung Cancer

5.10 Permanent Impairment Due to Respiratory Disorders

5.11 Respiratory Impairment Evaluation Summary

Introduction

This chapter provides criteria for evaluating permanent impairment of the respiratory system as it affects overall lung function and the ability to perform the activities of daily living. The respiratory system includes the tracheobronchial tree, pulmonary parenchyma, and ribcage.

The following sections have been revised for the fifth edition: (1) criteria for asthma impairment were updated to incorporate guidelines recently published by the American Thoracic Society (ATS)[1]; (2) respiratory impairment criteria now incorporate the lower limits of normal[2] for forced vital capacity (FVC), forced expiratory volume in the first second (FEV_1), and diffusing capacity for carbon monoxide (Dco); and (3) the section on sleep apnea has been updated to reflect current assessment and practice.

5.1 Principles of Assessment

Before using the information in this chapter, the *Guides* user should become familiar with Chapters 1 and 2 and the Glossary. Chapters 1 and 2 discuss the *Guides'* purpose, applications, and methods for performing and reporting impairment evaluations. The Glossary provides definitions of common terms used by many specialties in impairment evaluations.

The purpose of respiratory impairment assessment is to determine if a permanent respiratory impairment exists, quantify its severity, assess its impact on the ability to perform activities of daily living, and, if possible, identify the cause of the abnormality and recommend measures to prevent further impairment and ensure optimum function.

An impairment, as stated in Chapter 1, is "a loss, loss of use, or derangement of any body part, organ system, or organ function" (Table 1-1). Not all impairments result in a functional loss or affect the ability to perform activities of daily living. Respiratory impairments that produce a decrement of lung function and affect the ability to perform activities of daily living are assigned an impairment rating. For example, an anatomic change such as a circumscribed pleural plaque would be an impairment based on an abnormality in anatomic structure. However, if there were no abnormality in lung function and no decrease in the ability to perform activities of daily living, the individual would be assigned a 0% impairment rating.

Changes in organ function are the primary criteria for determining the impairment class. To establish the specific impairment percentage, consider both the severity and prognosis of the condition and how the impairment affects the individual's ability to perform the activities of daily living listed in Table 1-2. Table 5-13 is provided at the end of the chapter to ensure all pertinent information is included in the respiratory assessment.

Begin the evaluation with an inquiry into specific symptoms and their severity, duration, and manner of onset. Since environmental exposure frequently leads to symptomatic complaints, it is important to determine if the individual's personal habits or surroundings, such as cigarette smoking and workplace exposures, explain or contribute to the symptoms. A thorough history enables the examiner to direct the physical examination to areas of concern and then identify the most useful diagnostic and evaluative studies. For instance, structural and movement disorders of the chest wall or diaphragm found on physical examination would prompt different investigations than an observation of wheezing. Radiographic techniques such as chest roentgenograms or computed tomography (CT) scans help elucidate anatomic abnormalities that are sometimes diagnostic of specific disease processes. To assess impairment, weigh both subjective and objective information derived from thorough history-taking, physical examination, imaging and laboratory studies, and pulmonary function tests. These complementary evaluation techniques enable the examiner to obtain an accurate and thorough view of the impairment's nature, as well as the individual's limitations and ability to perform activities of daily living.

5.1a Interpretation of Symptoms and Signs

Symptomatic assessment of individuals with respiratory disease is diagnostically useful, but it provides limited quantitative information and should not serve as the sole criterion upon which to make decisions about impairment. Rather, the examiner should obtain objective data about the extent of the limitation and integrate those findings with the subjective data to estimate the degree of permanent impairment.

5.1b Description of Clinical Studies

Clinical studies used to assess pulmonary impairment include radiographs; other imaging studies, including CT scans and MR images; pulmonary function tests; and exercise testing. Pulmonary function tests are the most useful in assessing functional changes.

Chapter 5

5.2 Symptoms Associated With Respiratory Disease

The major symptoms of pulmonary disease include dyspnea; cough, sputum production, and hemoptysis; wheezing; and chest pain or tightness. The examiner needs to document these symptoms and their course over time, and correlate the symptoms with objective studies to assess their importance and implications. The significance of respiratory symptoms is better understood when integrated with findings from more objective measures such as the physical examination, radiography, lung function, and laboratory studies.

5.2a Dyspnea

Dyspnea is the most common symptom noted on initial examination of individuals with any type of pulmonary impairment. Despite its importance, dyspnea is nonspecific; it is often caused by cardiac, hematologic, metabolic, or neurologic disease, or by anxiety or physical deconditioning.

Dyspnea can be evaluated and quantitated using several systems. The most widely used classification system, developed with the ATS, (Table 5-1), is based on the American Thoracic Society/Division of Lung Diseases Respiratory Symptom questionnaire.[3] The ATS classification is best used in conjunction with more objective respiratory function measurements. If a disparity is found between subjective complaints of dyspnea and findings on respiratory testing, consider a nonrespiratory dyspnea component.[3]

Table 5-1 Impairment Classification of Dyspnea*

Severity	Definition and Question
Mild	Do you have to walk more slowly on the level than people of your age because of breathlessness?
Moderate	Do you have to stop for breath when walking at your own pace on the level?
Severe	Do you ever have to stop for breath after walking about 100 yards or for a few minutes on the level?
Very severe	Are you too breathless to leave the house, or breathless on dressing or undressing?

* The person's lowest level of physical activity and exertion that produces breathlessness denotes the severity of dyspnea.[3]

5.2b Cough, Sputum Production, and Hemoptysis

Coughing can be an important indicator of respiratory tract disease, although it is difficult to quantify and not easily measured. Document its presence or absence, whether it is productive or nonproductive of sputum, its relationship to work or other activities, its duration, its association with hemoptysis, and whether further investigation is warranted.

An acute, self-limited cough is most commonly due to infection or irritation. A subacute or recurrent, nonproductive cough may be a manifestation of asthma and should be investigated with pulmonary function testing. A chronic, productive cough may indicate bronchitis. According to ATS criteria, the term *chronic bronchitis* may be used to describe a sputum-producing cough that occurs on most days for at least 3 consecutive months a year for at least 2 consecutive years.[4]

Hemoptysis frequently accompanies bronchitis and pneumonia, usually as blood-streaked sputum. Serious conditions that often manifest with hemoptysis include bronchogenic carcinoma, pulmonary emboli, bronchiectasis, tuberculosis, aspergilloma, and arteriovenous malformations. At a minimum, hemoptysis requires radiologic evaluation that may uncover respiratory or other impairment-producing types of diseases.

5.2c Wheezing

Subjects with partial airway obstruction often report high-pitched, musical sounds, or wheezing. These sounds can be generated at any point along the respiratory tract from the glottis to the bronchioles. Inspiratory wheezing, or stridor, suggests laryngeal disease; expiratory wheezing indicates bronchospasm or localized bronchial narrowing. Information about seasonal wheezing is also diagnostically significant. Wheezing and/or cough occurring primarily in the workplace or having a definite temporal relationship to work suggests occupational asthma; wheezing that follows several minutes of exercise suggests exercise-induced asthma; and wheezing that usually accompanies respiratory tract infections is classified as asthmatic bronchitis. While these different varieties of asthma are commonly described as separate entities, there is substantial overlap among the syndromes. This is due to the underlying commonalities of airway hyperresponsiveness in all types of asthma.

5.2d Thoracic Cage Abnormalities

Osseous spine abnormalities may produce respiratory impairment due to mechanical factors involving the size of the chest cavity and restriction of rib motion. Kyphoscoliosis, the most common of these abnormalities, is characterized by curvature of the vertebral column from side to side in the frontal plane (scoliosis) and from the dorsal to the ventral aspect of the sagittal plane (kyphosis). The Cobb method is the most common measurement tool for curvature severity. With this method, posteroanterior and lateral spinal radiographs measure the curvature angles. Only severe curvature angles—that is, Cobb angles that are greater than 100°—are likely to lead to respiratory failure. Even when there are severe spinal deformities, respiratory decompensation usually does not occur until middle age or later.

With severe spinal abnormalities, respiratory compromise is produced by the combined effects of restricted lung volume, decreased cross-sectional area of the vascular bed, and age-related decrease in chest wall compliance. Progressive stiffness of the chest wall with advancing age increases the work of breathing and leads to hypoventilation, which produces hypoxia and hypercapnia. Hypoxia is a powerful pulmonary vasoconstrictor and further decreases the vascular cross-sectional area, eventually leading to cor pulmonale. Judge the severity of respiratory impairment on the criteria described in the sections on forced respiratory maneuvers (5.4d), diffusing capacity for carbon monoxide (5.4e), and the criteria for rating impairment due to respiratory disease (5.4g) in this chapter.

5.3 Tobacco Use and Environmental Exposure Associated With Respiratory Disease

5.3a Tobacco Use

Exposure to tobacco smoke is a common cause of respiratory impairment. Although susceptibility to the adverse effects of cigarette smoke varies, there is a discernible dose-response relationship. The examiner should ask the individual's current age; the age at which he or she started smoking; the average number of packs smoked per day if the smoking has continued; and, if the person quit smoking at any time, the age and date he or she quit smoking.

Multiply the number of years of smoking by the number of packs smoked per day to produce the standard measure of pack-years of cigarette smoking. Use this information to assess the impact of personal habits on respiratory impairment. Cigarette smoking is the most frequent causative factor in the development of chronic bronchitis, emphysema, and lung cancer, and it can exacerbate asthma. Chronic exposure to environmental tobacco smoke may also be a factor in the origin of lung cancer, and it can also exacerbate asthma. Smoking cessation should be noted since it often benefits respiratory status. Although the anatomic abnormalities of emphysema are irreversible, both bronchospasm and productive cough can be favorably affected by the discontinuation of cigarette use. In addition, risk of bronchogenic carcinoma decreases progressively in the first 10 to 15 years after quitting smoking. After that time, the risk stabilizes at a point slightly higher than that of someone who has never smoked.[5]

5.3b Environmental Exposure

Environmental exposures in the workplace often are cited as causative or contributory factors in the development of respiratory impairment. It is important to obtain a complete occupational history from the individual to evaluate the possible effect of these exposures. A chief component of the history contains a chronological description of work activities beginning with the first year of employment and includes names of employers, the specific types of work performed, the materials used by the person, and the potentially toxic materials present in the workplace. Employers are required to maintain a list (made available to the employee and the treating physician in the form of Material Safety Data Sheets) of potentially toxic materials used in the workplace, their chemical descriptions, and their physical and health hazards. This information can be quite helpful to the examiner to direct the diagnostic and evaluative process. To assess its significance, ask the individual to estimate the frequency and intensity of exposure to each substance, as well as information about the use of respiratory protective devices.

Respiratory injuries in the workplace can occur in several different patterns, depending on the nature of the inhaled material and the circumstances of exposure. Acute lung injury may be the result of inhalation of a highly irritative gas, fume, mist, or vapor that results in noncardiogenic pulmonary edema or acute respiratory distress syndrome. If the individual survives the acute lung injury, the healing process may produce diffuse pulmonary fibrosis or obliterative bronchiolitis, which may lead to functional impairment. Depending on the nature, duration, and intensity of exposure, inhalation of irritative substances can cause subsequent persistent problems such as chronic bronchitis and airway hyperreactivity. Allergic pulmonary reactions can result from inhalation of organic material or certain types of reactive chemical molecules, causing asthma or hypersensitivity pneumonitis. Inhalation of fibrogenic dust can cause pneumoconiosis over a prolonged period. Workplace exposures can also exacerbate underlying conditions such as asthma, chronic bronchitis, or emphysema.

In addition to information on workplace exposure, inquire about home and environmental exposure (including hobbies or leisure time activities) to organic and inorganic agents such as allergens, bioaerosols, paints, glues, or pesticides. In the home, exposure to pets and use of cool-mist vaporizers, humidifiers, and indoor hot tubs also may be associated with respiratory disease.

5.4 Examinations, Clinical Studies, and Other Tests for Evaluating Respiratory Disease

5.4a Physical Examination

Although a thorough physical examination is mandatory to reach valid conclusions about an individual's impairment, certain portions of the examination are particularly pertinent in evaluating the respiratory system. Observe and record respiratory rate, use of accessory muscles, and body habitus. Noisy breath sounds are a physical finding that may indicate airflow obstruction. A breathing pattern characterized by pursed lip breathing during expiration suggests chronic obstructive pulmonary disease (COPD). Inspect the thoracic cage for vertebral or rib cage deformity and movement of the ribs with inspiration and expiration. A barrel-shaped chest may indicate hyperinflation. Percuss the chest to ascertain hyperresonance or consolidation and assess diaphragmatic motion.

Chest auscultation detects decreased breath sounds, crackles, wheezes, or rhonchi. Describe the intensity, quality, and location of these, as well as whether they are heard during inspiration, [illegible]tion, or both. Inspiratory crackles, heard in [illegible] thirds of people with chronic interstitial lung [illegible]e, may be associated with restrictive respiratory impairment. Wheezes and rhonchi are indicative of bronchial abnormalities and are often accompanied by obstructive airway disease. Auscultate during both quiet breathing and forced expiration before excluding wheezing. Diffuse, bilateral, expiratory wheezing indicates generalized bronchospasm, while unilateral or localized wheezing may be caused by partial bronchial obstruction due to an endobronchial tumor or mucus plugging. Early inspiratory crackles or opening snaps may be heard in diseases of airflow obstruction and particularly in bronchiolitis obliterans.

Cyanosis, indicated by a bluish tint of the lips and nail beds, is a striking but unreliable indicator of severe pulmonary impairment. Poor lighting in the examination room, anemia, and skin pigmentation can interfere with assessment of severity. Suspicion of cyanosis calls for pulse oximetry or arterial blood gas analysis.

Digital clubbing is characterized by loss of the angle at the junction of the cuticle and the nail, softening of the nail bed, increased curvature of the nails, and widening of the distal portions of the fingers and toes. Chest diseases associated with clubbing include pulmonary fibrosis, bronchiectasis, bronchogenic carcinoma, pleural tumors, lung abscess, empyema, and cyanotic congenital heart disease.

5.4b Chest Roentgenograms

The initial radiographic examination should include posteroanterior and lateral views of the chest taken in full inspiration. Chest radiographic findings often correlate poorly with physiologic findings in diseases with airflow limitation, such as asthma and emphysema. Chronic radiographic abnormalities of the chest may be classified as parenchymal, bronchovascular, cardiovascular, pleural, or osseous. Mediastinal or tracheal changes may be observed. Terms used to describe parenchymal changes can be classified as hyperinflation, fibrosis, cavitary, or cystic.

Hyperinflation is characteristic of airway obstruction. Radiographic findings of hyperinflation are seen in airway obstruction, while volume restriction is associated with fibrosis, loss of chest wall compliance, or severe neuromuscular weakness. Severe chronic obstructive pulmonary disease is manifested radiographically by diaphragm flattening, attenuation of pulmonary vasculature within the parenchyma, increased anteroposterior diameter of the chest, and increased retrosternal air space. An individual with an acute asthmatic attack can have radiographic evidence of hyperinflation without parenchymal vascular attenuation; when the asthmatic attack dissipates, the radiographic appearance reverts to normal.

Diffuse fibrotic changes in the pulmonary parenchyma may appear linear (streaky) and/or nodular (rounded). Specific diagnostic information is obtained by noting both the type and the predominant location of fibrotic changes and whether they are focal or diffuse. For example, silicosis is manifested by nodular opacities that predominate in the upper portions of the chest, while asbestosis is manifested by linear opacities that typically are most marked in lower portions of the lungs. Pleural changes such as pleural plaques may also be present in individuals with asbestosis or may be the sole manifestation of past asbestos exposure.

The International Labor Organization (ILO) adopted a standardized method of classifying radiographic abnormalities associated with fibrotic changes caused by pneumoconiosis.[6] The National Institute for Occupational Safety and Health (NIOSH) regularly administers a course and examination to certify knowledge and proficiency in the use of this method. Information on courses and programs can be obtained from the NIOSH Division of Respiratory Disease Studies, Morgantown, WVa, or by calling 800 35-NIOSH.

Evidence of cardiovascular abnormalities associated with chronic pulmonary disease is suggested when chest films show evidence of pulmonary hypertension and/or cor pulmonale. Pulmonary hypertension is indicated by enlargement of pulmonary arteries in the hila and rapid tapering of the peripheral vessels. Cor pulmonale presents as an enlargement of the right ventricle and the radiographic indicators of pulmonary hypertension. The presence of pulmonary hypertension and/or cor pulmonale and the severity of those processes may need to be confirmed by additional clinical and laboratory tests.

5.4c Computed Tomography

Computed tomography (CT) and high-resolution computed tomography (HRCT) are radiographic techniques than can augment the standard chest radiograph and are more sensitive in evaluating certain pulmonary diseases such as asbestosis. Conventional CT is obtained using 10-mm-thick slices through various lung fields. This technique is good for evaluating nodules with high radiographic attenuation. The HRCT, which consists of 1- to 2-mm thick slices every 10 mm, is useful for evaluating changes with low radiographic attenuation such as early interstitial lung disease. The standard CT and/or HRCT can provide greater accuracy as part of a thorough assessment of the pulmonary parenchyma. It should be noted that, in general, the HRCT delivers significantly less whole body effective dose radiation than the standard CT.

With regard to airway disease, HRCT can detect early changes in the lung consistent with focal emphysema; regional air trapping associated with small airway disease, such as obliterative bronchiolitis; and large airway abnormalities, such as bronchiectasis. For example, air trapping of the type seen with obliterative bronchiolitis is best demonstrated by comparing full inspiratory and full expiratory scans. Prone and supine position scans also are helpful in distinguishing hydrostatic changes related to blood volume that are transient and can occur in the dependent position of the lungs from fixed parenchymal abnormalities.[7,8]

5.4d Forced Expiratory Maneuvers (Simple Spirometry)

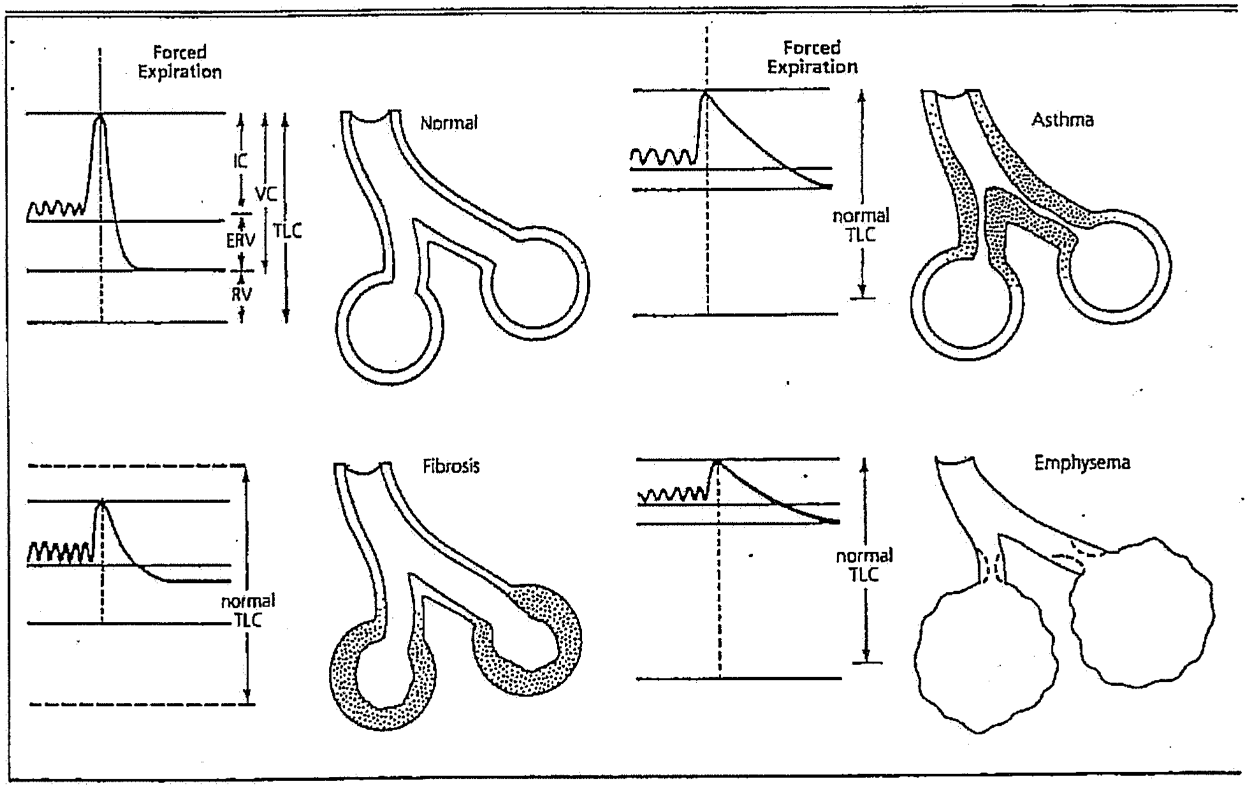
Pulmonary function tests, performed on standardized equipment with validated administration techniques, provide the framework for evaluation of respiratory system impairment. Spirometric testing equipment, calibration, and administration techniques must conform to the guidelines of the 1994 ATS Statement on Standardization of Spirometry.[9-15]

If tolerated by the individual, remove pulmonary medications up to 24 hours before spirometry or methacholine challenge testing to assess pulmonary function without the effects of medication.

Forced expiratory maneuver measurements are made from at least three acceptable spirometric tracings that demonstrate uniformity pertaining to both the expiratory flow pattern and concordance of at least two of the test results within 5% of each other. Measurements include the following: forced vital capacity (FVC), forced expiratory volume in the first second (FEV_1), and the ratio of these measurements (FEV_1/FVC). Use the tracings with the highest FVC and FEV_1 to calculate the FEV_1/FVC ratio, even if these measurements occur on different expiratory efforts.[12-14,16]

Repeat spirometry after bronchodilator administration if FEV_1/FVC is below 0.70 or if there is wheezing on physical examination. Use the spirogram indicating the best effort, before or after administration of a bronchodilator, to determine FVC and FEV_1 for impairment assessment. Postbronchodilator FEV_1 and FVC are important in understanding potential medication responsiveness and prognosis.[12,14,17,18]

Figure 5-1 Lung Capacities and Volumes in the Normal State and in Three Abnormal Conditions*



IC = inspiratory capacity; VC = vital capacity; TLC = total lung capacity; RV = residual volume; ERV = expiratory reserve volume.

*Residual volume, and therefore total lung capacity, cannot be measured by spirometry alone.

To use pulmonary function measures, obtain measurements of the FVC, FEV, and Dco and compare these to the predicted normal values as presented in Tables 5-2a through 5-7a. For the average or mean predicted normal value, find the individual's age in the left-hand column and height along the top row; the predicted value lies at the intersection of the appropriate row and column. In addition, identify the lower limit of normal for the measure of interest by using Tables 5-2b through 5-7b. The lower limit of normal has been calculated based upon the standard convention of the lower limit of normal lying at the fifth percentile, below the upper 95% of the reference population, according to recommendations from the ATS.[13,14] The lower limits of normal are used to distinguish between class 1 and class 2 respiratory impairment in Table 5-12.

North American whites have larger spirometric values for a given age, height, and gender than North American blacks, with a similar tendency noted for Hispanics, Native Americans, and Asians. Population values of normal lung function have been identified for blacks. The ATS Task Force for Interpretation of Pulmonary Function recommends an adjustment on a population basis for predicted lung function in blacks. Multiply values for predicted normal FVC (Tables 5-2a and 5-3a) by 0.88; for predicted normal FEV$_1$ (Tables 5-4a and 5-5a) by 0.88; and for normal single-breath Dco (Tables 5-6a and 5-7a) by 0.93. In cases where the correction value may not apply, the examiner may choose not to use this correction and instead may provide an explanation why it is inappropriate. Reliable population data are not yet available for other ethnic groups, such as Hispanics, Native Americans, and Asians. For these ethnic groups, the values for North American whites may be used.[16,19-21]

The FEV$_1$/FVC ratio helps diagnose obstructive airway disease. However, according to the most recent ATS statement on pulmonary function testing interpretation, the absolute volume or the percentage of predicted value of FEV$_1$ is the primary parameter for assessing severity of obstruction, although the FEV$_1$/FVC may be helpful.[11] Rather, judge severity on the absolute value or the percentage of predicted value of FEV$_1$.

5.4e Diffusing Capacity for Carbon Monoxide (Dco)

Use single-breath Dco to evaluate all levels of impairment. The single-breath Dco testing method is described in a 1995 ATS statement.[14,22] The Dco measurement provides information about gas transfer efficiency across the lungs.[23] Several physiologic factors affect the gas transfer process, including alveolar-capillary membrane thickness, available gas exchange surface area, gas solubility, pulmonary capillary blood volume, hematocrit, test gas concentration gradient across the alveolar-capillary membrane, and hemoglobin-binding site availability.

Mechanical factors that affect Dco results include gas inhalation speed, inspiration depth, period of breath holding, and expiration speed. While mechanical factors generally are controlled by Dco test automation, extrapulmonary factors are important to ascertain proper interpretation. For example, cigarette smoking can elevate the blood's carbon monoxide levels, causing as much as 10% to 12% hemoglobin saturation and decreasing Dco. Instruct the individual not to smoke for at least 8 hours before the test.

See Tables 5-6a and 5-7a for reference values for population-based predicted normal diffusing capacity. Use these tables in a manner similar to the spirometry tables. A laboratory that tests Dco under conditions or with procedures different than that recommended by the ATS should either develop and verify its own prediction equations or use an accepted and verified equation.

See Table 5-12 for classification of respiratory impairment based on the testing results of FVC, FEV$_1$, FEV$_1$/FVC, and Dco. Also consider the possible contribution of extrapulmonary factors to respiratory system impairment. For example, morbid obesity may decrease FVC, and anemia may decrease Dco. Evaluate other organ system impairments according to the criteria given in other *Guides* chapters and combine those impairment ratings with the respiratory system impairment rating (see the Combined Values Chart, p. 604).

Table 5-2a Predicted Normal Forced Vital Capacity (FVC) in Liters for Men (BTPS)*

Age	Height (cm) 146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	3.72	3.84	3.96	4.08	4.20	4.32	4.44	4.56	4.68	4.80	4.92	5.04	5.16	5.28	5.40	5.52	5.64	5.76	5.88	6.00	6.12	6.24	6.36	6.48	6.60
20	3.68	3.80	3.92	4.04	4.16	4.28	4.40	4.52	4.64	4.76	4.88	5.00	5.12	5.24	5.36	5.48	5.60	5.72	5.84	5.96	6.08	6.20	6.32	6.44	6.56
22	3.64	3.76	3.88	4.00	4.12	4.24	4.36	4.48	4.60	4.72	4.84	4.96	5.08	5.20	5.32	5.44	5.56	5.68	5.80	5.92	6.04	6.16	6.28	6.40	6.52
24	3.60	3.72	3.84	3.95	4.08	4.20	4.32	4.44	4.56	4.68	4.80	4.92	5.04	5.16	5.28	5.40	5.52	5.64	5.76	5.88	6.00	6.12	6.24	6.36	6.48
26	3.55	3.67	3.79	3.91	4.03	4.15	4.27	4.39	4.51	4.63	4.75	4.87	4.99	5.11	5.23	5.35	5.47	5.59	5.71	5.83	5.95	6.07	6.19	6.31	6.43
28	3.51	3.63	3.75	3.87	3.99	4.11	4.23	4.35	4.47	4.59	4.71	4.83	4.95	5.07	5.19	5.31	5.43	5.55	5.67	5.79	5.91	6.03	6.15	6.27	6.39
30	3.47	3.59	3.71	3.83	3.95	4.07	4.19	4.31	4.43	4.55	4.67	4.79	4.91	5.03	5.15	5.27	5.39	5.51	5.63	5.75	5.87	5.99	6.11	6.23	6.35
32	3.43	3.55	3.67	3.79	3.91	4.03	4.15	4.27	4.39	4.51	4.63	4.75	4.87	4.99	5.11	5.23	5.35	5.47	5.59	5.71	5.83	5.95	6.07	6.19	6.31
34	3.38	3.50	3.62	3.74	3.86	3.98	4.10	4.22	4.34	4.46	4.58	4.70	4.82	4.94	5.06	5.18	5.30	5.42	5.54	5.66	5.78	5.90	6.02	6.14	6.26
36	3.34	3.46	3.58	3.70	3.82	3.94	4.06	4.18	4.30	4.42	4.54	4.66	4.78	4.90	5.02	5.14	5.26	5.38	5.50	5.62	5.74	5.86	5.98	6.10	6.22
38	3.30	3.42	3.54	3.66	3.78	3.90	4.02	4.14	4.26	4.38	4.50	4.62	4.74	4.86	4.98	5.10	5.22	5.34	5.46	5.58	5.70	5.82	5.94	6.06	6.18
40	3.25	3.37	3.49	3.61	3.73	3.85	3.97	4.09	4.21	4.33	4.45	4.57	4.69	4.81	4.93	5.05	5.17	5.29	5.41	[illegible]	[illegible]	5.77	5.89	6.01	6.13
42	3.21	3.33	3.45	3.57	3.69	3.81	3.93	4.05	4.17	4.29	4.41	4.53	4.65	4.77	[illegible]	5.01	5.13	5.25	5.37	[illegible]	[illegible]	5.73	5.85	5.97	6.09
44	3.17	3.29	3.41	3.53	3.65	3.77	3.89	4.01	4.13	4.25	4.37	4.49	4.61	4.73	[illegible]	4.97	5.09	5.21	5.33	[illegible]	[illegible]	5.69	[illegible]	5.93	6.05
46	[illegible]	3.25	3.37	3.49	3.61	3.73	3.85	3.97	[illegible]	[illegible]	4.33	4.45	4.57	4.69	4.81	4.93	5.05	5.17	5.29	[illegible]	[illegible]	5.65	[illegible]	5.89	[illegible]
48	3.08	3.20	3.32	3.44	3.56	3.68	3.80	3.92	4.04	4.16	4.28	4.40	4.52	4.64	4.76	4.88	5.00	5.12	5.24	[illegible]	[illegible]	5.60	5.72	5.84	[illegible]
50	3.04	3.16	3.28	3.40	3.52	3.64	3.76	3.88	4.00	4.12	4.24	4.36	4.48	4.60	4.72	4.84	4.96	5.08	5.20	5.32	5.44	5.56	5.68	5.80	[illegible]
52	3.00	3.12	3.24	3.36	3.48	3.60	3.72	3.84	3.96	4.08	4.20	4.32	4.44	4.56	4.68	4.80	4.92	5.04	5.16	5.28	5.40	5.52	5.64	5.76	5.88
54	2.95	3.07	3.19	3.31	3.43	3.55	3.67	3.79	3.91	4.03	4.15	4.27	4.39	4.51	4.63	4.75	4.87	4.99	5.11	5.23	5.35	5.47	5.59	5.71	5.83
56	2.91	3.03	3.15	3.27	3.39	3.51	3.63	3.75	3.87	3.99	4.11	4.23	4.35	4.47	4.59	4.71	4.83	4.95	5.07	5.19	5.31	5.43	5.55	5.67	5.79
58	2.87	2.99	3.11	3.23	3.35	3.47	3.59	3.71	3.83	3.95	4.07	4.19	4.31	4.43	4.55	4.67	4.79	4.91	5.03	5.15	5.27	5.39	5.51	5.63	5.75
60	2.83	2.95	3.07	3.19	3.31	3.43	3.55	3.67	3.79	3.91	4.03	4.15	4.27	4.39	4.51	4.63	4.75	4.87	4.99	5.11	5.23	5.35	5.47	5.59	5.71
62	2.78	2.90	3.02	3.14	3.26	3.38	3.50	3.62	3.74	3.86	3.98	4.10	4.22	3.34	4.46	4.58	4.70	4.82	4.94	5.06	5.18	5.30	5.42	5.54	5.66
64	2.74	2.86	2.98	3.10	3.22	3.34	3.46	3.58	3.70	3.82	3.94	4.06	4.18	4.30	4.42	4.54	4.66	4.78	4.90	5.02	5.14	5.26	5.38	5.50	5.62
66	2.70	2.82	2.94	3.06	3.18	3.30	3.42	3.54	3.66	3.78	3.90	4.02	4.14	4.26	4.38	4.50	4.62	4.74	4.86	4.98	5.10	5.22	5.34	5.46	5.58
68	2.65	2.77	2.89	3.01	3.13	3.25	3.37	3.49	3.61	3.73	3.85	3.97	4.09	4.21	4.33	4.45	4.57	4.69	4.81	4.93	5.05	5.17	5.29	5.41	5.53
70	2.61	2.73	2.85	2.97	3.09	3.21	3.33	3.45	3.57	3.69	3.81	3.93	4.05	4.17	4.29	4.41	4.53	4.65	4.77	4.89	5.01	5.13	5.25	5.37	5.49
72	2.57	2.69	2.81	2.93	3.05	3.17	3.29	3.41	3.53	3.65	3.77	3.89	4.01	4.13	4.25	4.37	4.49	4.61	4.73	4.85	4.97	5.09	5.21	5.33	5.45
74	2.53	2.65	2.77	2.89	3.01	3.13	3.25	3.37	3.49	3.61	3.73	3.85	3.97	4.09	4.21	4.33	4.45	4.57	4.69	4.81	4.93	5.05	5.17	5.29	5.41

*FVC in liters = 0.0600 H − 0.0214 A − 4.650. R^2 = 0.54; SEE = 0.644; 95% confidence level = 1.115. Definitions of abbreviations: R^2 = coefficient of determination; SEE = standard error of estimate; H = height in cm; A = age in years. BTPS = body temperature, ambient pressure, and saturated with water vapor at these conditions. Adapted from Crapo et al.[2]

Table 5-2b Predicted Lower Limit of Normal Forced Vital Capacity (FVC) for Men*

Age	Height (cm) 146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	2.605	2.725	2.845	2.965	3.085	3.205	3.325	3.445	3.565	3.685	3.805	3.925	4.045	4.165	4.285	4.405	4.525	4.645	4.765	4.885	5.005	5.125	5.245	5.365	5.485
20	2.565	2.685	2.805	2.925	3.045	3.165	3.285	3.405	3.525	3.645	3.765	3.885	4.005	4.125	4.245	4.365	4.485	4.605	4.725	4.845	4.965	5.085	5.205	5.325	5.445
22	2.525	2.645	2.765	2.885	3.005	3.125	3.245	3.365	3.485	3.605	3.725	3.845	3.965	4.085	4.205	4.325	4.445	4.565	4.685	4.805	4.925	5.045	5.165	5.285	5.405
24	2.485	2.605	2.725	2.835	2.965	3.085	3.205	3.325	3.445	3.565	3.685	3.805	3.925	4.045	4.165	4.285	4.405	4.525	4.645	4.765	4.885	5.005	5.125	5.245	5.365
26	2.435	2.555	2.675	2.795	2.915	3.035	3.155	3.275	3.395	3.515	3.635	3.755	3.875	3.995	4.115	4.235	4.355	4.475	4.595	4.715	4.835	4.955	5.075	5.195	5.315
28	2.395	2.515	2.635	2.755	2.875	2.995	3.115	3.235	3.355	3.475	3.595	3.715	3.835	3.955	4.075	4.195	4.315	4.435	4.555	4.675	4.795	4.915	5.035	5.155	5.275
30	2.355	2.475	2.595	2.715	2.835	2.955	3.075	3.195	3.315	3.435	3.555	3.675	3.795	3.915	4.035	4.155	4.275	4.395	4.515	4.635	4.755	4.875	4.995	5.115	5.235
32	2.315	2.435	2.555	2.675	2.795	2.915	3.035	3.155	3.275	3.395	3.515	3.635	3.755	3.875	3.995	4.115	4.235	4.355	4.475	4.595	4.715	4.835	4.955	5.075	5.195
34	2.265	2.385	2.505	2.625	2.745	2.865	2.985	3.105	3.225	3.345	3.465	3.585	3.705	3.825	3.945	4.065	4.185	4.305	4.425	4.545	4.665	4.785	4.905	5.025	5.145
36	2.225	2.345	2.465	2.585	2.705	2.825	2.945	3.065	3.185	3.305	3.425	3.545	3.665	3.785	3.905	4.025	4.145	4.265	4.385	4.505	4.625	4.745	4.865	4.985	5.105
38	2.185	2.305	2.425	2.545	2.665	2.785	2.905	3.025	3.145	3.265	3.385	3.505	3.625	3.745	3.865	3.985	4.105	4.225	4.345	4.465	4.585	4.705	4.825	4.945	5.065
40	2.135	2.255	2.375	2.495	2.615	2.735	2.855	2.975	3.095	3.215	3.335	3.455	3.575	3.695	3.815	3.935	4.055	4.175	4.295	4.415	4.535	4.655	4.775	4.895	5.015
42	2.095	2.215	2.335	2.455	2.575	2.695	2.815	2.935	3.055	3.175	3.295	3.415	3.535	3.655	3.775	3.895	4.015	4.135	4.255	4.375	4.495	4.615	4.735	4.855	4.975
44	2.055	2.175	2.295	2.415	2.535	2.655	2.775	2.895	3.015	3.135	3.255	3.375	3.495	3.615	3.735	3.855	3.975	4.095	4.215	4.335	4.455	4.575	4.695	4.815	4.935
46	2.015	2.135	2.255	2.375	2.495	2.615	2.735	2.855	2.975	3.095	3.215	3.335	3.455	3.575	3.695	3.815	3.935	4.055	4.175	4.295	4.415	4.535	4.655	4.775	4.895
48	1.965	2.085	2.205	2.325	2.445	2.565	2.685	2.805	2.925	3.045	3.165	3.285	3.405	3.525	3.645	3.765	3.885	4.005	4.125	4.245	4.365	4.485	4.605	4.725	4.845
50	1.925	2.045	2.165	2.285	2.405	2.525	2.645	2.765	2.885	3.005	3.125	3.245	3.365	3.485	3.605	3.725	3.845	3.965	4.085	4.205	4.325	4.445	4.565	4.685	4.805
52	1.885	2.005	2.125	2.245	2.365	2.485	2.605	2.725	2.845	2.965	3.085	3.205	3.325	3.445	3.565	3.685	3.805	3.925	4.045	4.165	4.285	4.405	4.525	4.645	4.765
54	1.835	1.955	2.075	2.195	2.315	2.435	2.555	2.675	2.795	2.915	3.035	3.155	3.275	3.395	3.515	3.635	3.755	3.875	3.995	4.115	4.235	4.355	4.475	4.595	4.715
56	1.795	1.915	2.035	2.155	2.275	2.395	2.515	2.635	2.755	2.875	2.995	3.115	3.235	3.355	3.475	3.595	3.715	3.835	3.955	4.075	4.195	4.315	4.435	4.555	4.675
58	1.755	1.875	1.995	2.115	2.235	2.355	2.475	2.595	2.715	2.835	2.955	3.075	3.195	3.315	3.435	3.555	3.675	3.795	3.915	4.035	4.155	4.275	4.395	4.515	4.635
60	1.715	1.835	1.955	2.075	2.195	2.315	2.435	2.555	2.675	2.795	2.915	3.035	3.155	3.275	3.395	3.515	3.635	3.755	3.875	3.995	4.115	4.235	4.355	4.475	4.595
62	1.665	1.785	1.905	2.025	2.145	2.265	2.385	2.505	2.625	2.745	2.865	2.985	3.105	2.225	3.345	3.465	3.585	3.705	3.825	3.945	4.065	4.185	4.305	4.425	4.545
64	1.625	1.745	1.865	1.985	2.105	2.225	2.345	2.465	2.585	2.705	2.825	2.945	3.065	3.185	3.305	3.425	3.545	3.665	3.785	3.905	4.025	4.145	4.265	4.385	4.505
66	1.585	1.705	1.825	1.945	2.065	2.185	2.305	2.425	2.545	2.665	2.785	2.905	3.025	3.145	3.265	3.385	3.505	3.625	3.745	3.865	3.985	4.105	4.225	4.345	4.465
68	1.535	1.655	1.775	1.895	2.015	2.135	2.255	2.375	2.495	2.615	2.735	2.855	2.975	3.095	3.215	3.335	3.455	3.575	3.695	3.815	3.935	4.055	4.175	4.295	4.415
70	1.495	1.615	1.735	1.855	1.975	2.095	2.215	2.335	2.455	2.575	2.695	2.815	2.935	3.055	3.175	3.295	3.415	3.535	3.655	3.775	3.895	4.015	4.135	4.255	4.375
72	1.455	1.575	1.695	1.815	1.935	2.055	2.175	2.295	2.415	2.535	2.655	2.775	2.895	3.015	3.135	3.255	3.375	3.495	3.615	3.735	3.855	3.975	4.095	4.215	4.335
74	1.415	1.535	1.655	1.775	1.895	2.015	2.135	2.255	2.375	2.495	2.615	2.735	2.855	2.975	3.095	3.215	3.335	3.455	3.575	3.695	3.815	3.935	4.055	4.175	3.180

*FVC values are given in liters. The values listed here reflect the FVC as listed in Table 5-2a minus 1.115 L (95% confidence interval). Adapted from Crapo et al.[2]

Table 5-3a Predicted Normal Forced Vital Capacity (FVC) in Liters for Women (BTPS)*

Age	Height (cm) 146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	3.19	3.29	3.39	3.48	3.58	3.68	3.78	3.88	3.98	4.07	4.17	4.27	4.37	4.47	4.56	4.66	4.76	4.86	4.96	5.06	5.15	5.25	5.35	5.45	5.55
20	3.15	3.24	3.34	3.44	3.54	3.64	3.74	3.83	3.93	4.03	4.13	4.23	4.32	4.42	4.52	4.62	4.72	4.82	4.91	5.01	5.11	5.21	5.31	5.41	5.50
22	3.10	3.20	3.30	3.40	3.50	3.59	3.69	3.79	3.89	3.99	4.09	4.18	4.28	4.38	4.48	4.58	4.67	4.77	4.87	4.97	5.07	5.17	5.26	5.36	5.46
24	3.06	3.16	3.26	3.35	3.45	3.55	3.65	3.75	3.85	3.94	4.04	4.14	4.24	4.34	4.43	4.53	4.63	4.73	4.83	4.93	5.02	5.12	5.22	5.32	5.42
26	3.02	3.12	3.21	3.31	3.41	3.51	3.61	3.70	3.80	3.90	4.00	4.10	4.20	4.29	4.39	4.49	4.59	4.69	4.78	4.88	4.98	5.08	5.18	5.28	5.37
28	2.97	3.07	3.17	3.27	3.37	3.46	3.56	3.66	3.76	3.86	3.96	4.05	4.15	4.25	4.35	4.45	4.54	4.64	4.74	4.84	4.94	5.04	5.13	5.23	5.33
30	2.93	3.03	3.13	3.23	3.32	3.42	3.52	3.62	3.72	3.81	3.91	4.01	4.11	4.21	4.31	4.40	4.50	4.60	4.70	4.80	4.89	4.99	5.09	5.19	5.29
32	2.89	2.99	3.08	3.18	3.28	3.38	3.48	3.57	3.67	3.77	3.87	3.97	4.07	4.16	4.26	4.36	4.46	4.56	4.65	4.75	4.85	4.95	5.05	5.15	5.24
34	2.84	2.94	3.04	3.14	3.24	3.34	3.43	3.53	3.63	3.73	3.83	3.92	4.02	4.12	4.22	4.32	4.42	4.51	4.61	4.71	4.81	4.91	5.00	5.10	5.20
36	2.80	2.90	3.00	3.10	3.19	3.29	3.39	3.49	3.59	3.68	3.78	3.88	3.98	4.08	4.18	4.27	4.37	4.47	4.57	4.67	4.76	4.86	4.96	5.06	5.16
38	2.76	2.86	2.95	3.05	3.15	3.25	3.35	3.45	3.54	3.64	3.74	3.84	3.94	4.03	4.13	4.23	4.33	4.43	4.53	4.62	4.72	4.82	4.92	5.02	5.11
40	2.71	2.81	2.91	3.01	3.11	3.21	3.30	3.40	3.50	3.60	3.70	3.79	3.89	3.99	4.09	4.19	4.29	4.38	4.48	4.58	4.68	4.78	4.87	4.97	5.07
42	2.67	2.77	2.87	2.97	3.06	3.16	3.26	3.36	3.46	3.56	3.65	3.75	3.85	3.95	4.05	4.14	4.24	4.34	4.44	4.54	4.64	4.73	[illegible]	[illegible]	5.03
44	2.63	2.73	2.82	2.92	3.02	3.12	3.22	3.32	3.41	3.51	3.61	3.71	3.81	3.90	4.00	4.10	4.20	4.30	4.40	4.49	[illegible]	[illegible]	[illegible]	[illegible]	4.98
46	2.58	2.68	2.78	2.88	2.98	3.08	3.17	3.27	3.37	3.47	3.57	3.67	3.76	3.86	3.96	4.06	4.16	4.25	4.35	4.45	4.55	[illegible]	4.75	[illegible]	4.94
48	2.54	2.64	2.74	2.84	2.93	3.03	3.13	3.23	3.33	3.43	3.52	3.62	3.72	3.82	3.92	4.01	4.11	4.21	4.31	4.41	4.51	4.60	4.70	[illegible]	4.90
50	2.50	2.60	2.69	2.79	2.89	2.99	3.09	3.19	3.28	3.38	3.48	3.58	3.68	3.78	3.87	3.97	4.07	4.17	4.27	4.36	4.46	4.56	4.66	4.76	4.86
52	2.46	2.55	2.65	2.75	2.85	2.95	3.04	3.14	3.24	3.34	3.44	3.54	3.63	3.73	3.83	3.93	4.03	4.12	4.22	4.32	4.42	4.52	4.62	4.71	4.81
54	2.41	2.51	2.61	2.71	2.80	2.90	3.00	3.10	3.20	3.30	3.39	3.49	3.59	3.69	3.79	3.89	3.98	4.08	4.18	4.28	4.38	4.47	4.57	4.67	4.77
56	2.37	2.47	2.57	2.66	2.76	2.86	2.96	3.06	3.15	3.25	3.35	3.45	3.55	3.65	3.74	3.84	3.94	4.04	4.14	4.23	4.33	4.43	4.53	4.63	4.73
58	2.33	2.42	2.52	2.62	2.72	2.82	2.91	3.01	3.11	3.21	3.31	3.41	3.50	3.60	3.70	3.80	3.90	4.00	4.09	4.19	4.29	4.39	4.49	4.58	4.68
60	2.28	2.38	2.48	2.58	2.68	2.77	2.87	2.97	3.07	3.17	3.26	3.36	3.46	3.56	3.66	2.76	3.85	3.95	4.05	4.15	4.25	4.34	4.44	4.54	4.64
62	2.24	2.34	2.44	2.53	2.63	2.73	2.83	2.93	3.02	3.12	3.22	3.32	3.42	3.52	3.61	3.71	3.81	3.91	4.01	4.11	4.20	4.30	4.40	4.50	4.60
64	2.20	2.29	2.39	2.49	2.59	2.69	2.79	2.88	2.98	3.08	3.18	3.28	3.37	3.47	3.57	3.67	3.77	3.87	3.96	4.06	4.16	4.26	4.36	4.45	4.55
66	2.15	2.25	2.35	2.45	2.55	2.64	2.74	2.84	2.94	3.04	3.14	3.23	3.33	3.43	3.53	3.63	3.72	3.82	3.92	4.02	4.12	4.22	4.31	4.41	4.51
68	2.11	2.21	2.31	2.40	2.50	2.60	2.70	2.80	2.90	2.99	3.09	3.19	3.29	3.39	3.48	3.58	3.68	3.78	3.88	3.98	4.07	4.17	4.27	4.37	4.47
70	2.07	2.16	2.26	2.36	2.46	2.56	2.66	2.75	2.85	2.95	3.05	3.15	3.24	3.34	3.44	3.54	3.64	3.74	3.83	3.93	4.03	4.13	4.23	4.33	4.42
72	2.02	2.12	2.22	2.32	2.42	2.51	2.61	2.71	2.81	2.91	3.01	3.10	3.20	3.30	3.40	3.50	3.59	3.69	3.79	3.89	3.99	4.09	4.18	4.28	4.38
74	1.98	2.08	2.18	2.27	2.37	2.47	2.57	2.67	2.77	2.86	2.96	3.06	3.16	3.26	3.36	3.45	3.55	3.65	3.75	3.85	3.94	4.04	4.14	4.24	4.34

*FVC in liters = 0.0491 H − 0.0216 A − 3.590, R^2 = 0.74; SEE = 0.393; 95% confidence interval = 0.676. Definitions of abbreviations: R^2 = coefficient of determination; SEE = standard error of estimate; H = height in cm; A = age in years, BTPS = body temperature, ambient pressure, and saturated with water vapor at these conditions. Adapted from Crapo et al.[3]

Table 5-3b Predicted Lower Limit of Normal Forced Vital Capacity (FVC) for Women*

Age	Height (cm) 146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	2.514	2.614	2.714	2.804	2.904	3.004	3.104	3.204	3.304	3.394	3.494	3.594	3.694	3.794	3.884	3.984	4.084	4.184	4.284	4.384	4.474	4.574	4.674	4.774	4.874
20	2.474	2.564	2.664	2.764	2.864	2.964	3.064	3.154	3.254	3.354	3.454	3.554	3.644	3.744	3.844	3.944	4.044	4.144	4.234	4.334	4.434	4.534	4.634	4.734	4.824
22	2.424	2.524	2.624	2.724	2.824	2.914	3.014	3.114	3.214	3.314	3.414	3.504	3.604	3.704	3.804	3.904	3.994	4.094	4.194	4.294	4.394	4.494	4.584	4.684	4.784
24	2.384	2.484	2.584	2.674	2.774	2.874	2.974	3.074	3.174	3.264	3.364	3.464	3.564	3.664	3.754	3.854	3.954	4.054	4.154	4.254	4.344	4.444	4.544	4.644	4.744
26	2.344	2.444	2.534	2.634	2.734	2.834	2.934	3.024	3.124	3.224	3.324	3.424	3.524	3.614	3.714	3.814	3.914	4.014	4.104	4.204	4.304	4.404	4.504	4.604	4.694
28	2.294	2.394	2.494	2.594	2.694	2.784	2.884	2.984	3.084	3.184	3.284	3.374	3.474	3.574	3.674	3.774	3.864	3.964	4.064	4.164	4.264	4.364	4.454	4.554	4.654
30	2.254	2.354	2.454	2.554	2.644	2.744	2.844	2.944	3.044	3.134	3.234	3.334	3.434	3.534	3.634	3.724	3.824	3.924	4.024	4.124	4.214	4.314	4.414	4.514	4.614
32	2.214	2.314	2.404	2.504	2.604	2.704	2.804	2.894	2.994	3.094	3.194	3.294	3.394	3.484	3.584	3.684	3.784	3.884	3.974	4.074	4.174	4.274	4.374	4.474	4.564
34	2.164	2.264	2.364	2.464	2.564	2.664	2.754	2.854	2.954	3.054	3.154	3.244	3.344	3.444	3.544	3.644	3.744	3.834	3.934	4.034	4.134	4.234	4.324	4.424	4.524
36	2.124	2.224	2.324	2.424	2.514	2.614	2.714	2.814	2.914	3.004	3.104	3.204	3.304	3.404	3.504	3.594	3.694	3.794	3.894	3.994	4.084	4.184	4.284	4.384	4.484
38	2.084	2.184	2.274	2.374	2.474	2.574	2.674	2.774	2.864	2.964	3.064	3.164	3.264	3.354	3.454	3.554	3.654	3.754	3.854	3.944	4.044	4.144	4.244	4.344	4.434
40	2.034	2.134	2.234	2.334	2.434	2.534	2.624	2.724	2.824	2.924	3.024	3.114	3.214	3.314	3.414	3.514	3.614	3.704	3.804	3.904	4.004	4.104	4.194	4.294	4.394
42	1.994	2.094	2.194	2.294	2.384	2.484	2.584	2.684	2.784	2.884	2.974	3.074	3.174	3.274	3.374	3.464	3.564	3.664	3.764	3.864	3.964	4.054	4.154	4.254	4.354
44	1.954	2.054	2.144	2.244	2.344	2.444	2.544	2.644	2.734	2.834	2.934	3.034	3.134	3.224	3.324	3.424	3.524	3.624	3.724	3.814	3.914	4.014	4.114	4.214	4.304
46	1.904	2.004	2.104	2.204	2.304	2.404	2.494	2.594	2.694	2.794	2.894	2.994	3.084	3.184	3.284	3.384	3.484	3.574	3.674	3.774	3.874	3.974	4.074	4.164	4.264
48	1.864	1.964	2.064	2.164	2.254	2.354	2.454	2.554	2.654	2.754	2.844	2.944	3.044	3.144	3.244	3.334	3.434	3.534	3.634	3.734	3.834	3.924	4.024	4.124	4.224
50	1.824	1.924	2.014	2.114	2.214	2.314	2.414	2.514	2.604	2.704	2.804	2.904	3.004	3.104	3.194	3.294	3.394	3.494	3.594	3.684	3.784	3.884	3.984	4.084	4.184
52	1.784	1.874	1.974	2.074	2.174	2.274	2.364	2.464	2.564	2.664	2.764	2.864	2.954	3.054	3.154	3.254	3.354	3.444	3.544	3.644	3.744	3.844	3.944	4.034	4.134
54	1.734	1.834	1.934	2.034	2.124	2.224	2.324	2.424	2.524	2.624	2.714	2.814	2.914	3.014	3.114	3.214	3.304	3.404	3.504	3.604	3.704	3.794	3.894	3.994	4.094
56	1.694	1.794	1.894	1.984	2.084	2.184	2.284	2.384	2.474	2.574	2.674	2.774	2.874	2.974	3.064	3.164	3.264	3.364	3.464	3.554	3.654	3.754	3.854	3.954	4.054
58	1.654	1.744	1.844	1.944	2.044	2.144	2.234	2.334	2.434	2.534	2.634	2.734	2.824	2.924	3.024	3.124	3.224	3.324	3.414	3.514	3.614	3.714	3.814	3.904	4.004
60	1.604	1.704	1.804	1.904	2.004	2.094	2.194	2.294	2.394	2.494	2.584	2.684	2.784	2.884	2.984	2.084	3.174	3.274	3.374	3.474	3.574	3.664	3.764	3.864	3.964
62	1.564	1.664	1.764	1.854	1.954	2.054	2.154	2.254	2.344	2.444	2.544	2.644	2.744	2.844	2.934	3.034	3.134	3.234	3.334	3.434	3.524	3.624	3.724	3.824	3.924
64	1.524	1.614	1.714	1.814	1.914	2.014	2.114	2.204	2.304	2.404	2.504	2.604	2.694	2.794	2.894	2.994	3.094	3.194	3.284	3.384	3.484	3.584	3.684	3.774	3.874
66	1.474	1.574	1.674	1.774	1.874	1.964	2.064	2.164	2.264	2.364	2.464	2.554	2.654	2.754	2.854	2.954	3.044	3.144	3.244	3.344	3.444	3.544	3.634	3.734	3.834
68	1.434	1.534	1.634	1.724	1.824	1.924	2.024	2.124	2.224	2.314	2.414	2.514	2.614	2.714	2.804	2.904	3.004	3.104	3.204	3.304	3.394	3.494	3.594	3.694	3.794
70	1.394	1.484	1.584	1.684	1.784	1.884	1.984	2.074	2.174	2.274	2.374	2.474	2.564	2.664	2.764	2.864	2.964	3.064	3.154	3.254	3.354	3.454	3.554	3.654	3.744
72	1.344	1.444	1.544	1.644	1.744	1.834	1.934	2.034	2.134	2.234	2.334	2.424	2.524	2.624	2.724	2.824	2.914	3.014	3.114	3.214	3.314	3.414	3.504	3.604	3.704
74	1.304	1.404	1.504	1.594	1.694	1.794	1.894	1.994	2.094	2.184	2.284	2.384	2.484	2.584	2.684	2.774	2.874	2.974	3.074	3.174	3.264	3.364	3.464	3.564	3.664

*FVC values are given in liters. The values listed here reflect the FVC as listed in Table 5-3a minus 0.676 L (95% confidence interval). Adapted from Crapo et al.[3]

Table 5-4a Predicted Normal Forced Expiratory Volume in the First Second (FEV_1) in Liters for Men*

Age	Height (cm) 146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	3.42	3.50	3.58	3.66	3.75	3.83	3.91	3.99	4.08	4.16	4.24	4.33	4.41	4.49	4.57	4.66	4.74	4.82	4.91	4.99	5..07	5.15	5.24	5.32	5.40
20	3.37	3.45	3.53	3.61	3.70	3.78	3.86	3.95	4.03	4.11	4.19	4.28	4.36	4.44	4.53	4.61	4.69	4.77	4.86	4.94	5.02	5.11	5.19	5.27	5.35
22	3.32	3.40	3.48	3.57	3.65	3.73	3.81	3.90	3.98	4.06	4.15	4.23	4.31	4.39	4.48	4.56	4.64	4.73	4.81	4.89	4.97	5.05	5.14	5.22	5.30
24	3.27	3.35	3.43	3.52	3.60	3.68	3.77	3.85	3.93	4.01	4.10	4.18	4.26	4.35	4.43	4.51	4.59	4.68	4.76	4.84	4.92	5.01	5.09	5.17	5.26
26	3.22	3.30	3.39	3.47	3.55	3.63	3.72	3.80	3.88	3.97	4.05	4.13	4.21	4.30	4.38	4.46	4.54	4.63	4.71	4.79	4.88	4.90	5.04	5.12	5.21
28	3.17	3.25	3.34	3.42	3.50	3.59	3.67	3.75	3.83	3.92	4.00	4.08	4.16	4.25	4.33	4.41	4.50	4.58	4.66	4.74	4.83	4.91	4.99	5.08	5.16
30	3.12	3.21	3.29	3.37	3.45	3.54	3.62	3.70	3.78	3.87	3.95	4.03	4.12	4.20	4.28	4.36	4.45	4.53	4.61	4.70	4.78	4.86	4.94	5.03	5.11
32	3.07	3.16	3.24	3.32	3.40	3.49	3.57	3.65	3.74	3.82	3.90	3.98	4.07	4.15	4.23	4.32	4.40	4.48	4.56	4.65	4.73	4.81	4.90	4.98	5.06
34	3.02	3.11	3.19	3.27	3.36	3.44	3.52	3.60	3.69	3.77	3.85	3.94	4.02	4.10	4.18	4.27	4.35	4.43	4.52	4.60	4.68	4.76	4.85	4.93	5.01
36	2.98	3.06	3.14	3.22	3.31	3.39	3.47	3.56	3.64	3.72	3.80	3.89	3.97	4.05	4.14	4.22	4.30	4.38	4.47	4.55	4.63	4.71	4.80	4.88	4.96
38	2.93	3.01	3.09	3.18	3.26	3.34	3.42	3.51	3.59	3.67	3.76	3.84	3.92	4.00	4.09	4.17	4.25	4.33	4.42	4.50	4.58	4.67	4.75	4.83	4.91
40	2.88	2.96	3.04	3.13	3.21	3.29	3.38	3.46	3.54	3.62	3.71	3.79	3.87	3.95	4.04	4.12	4.20	4.29	4.37	4.45	4.53	4.62	4.70	4.78	4.87
42	2.83	2.91	3.00	3.08	3.16	3.24	3.33	3.41	3.49	3.57	3.66	3.74	3.82	3.91	3.99	4.07	4.15	4.24	4.32	4.40	4.49	4.57	4.65	4.73	4.82
44	2.78	2.86	2.95	3.03	3.11	3.19	3.28	3.36	3.44	3.53	3.61	3.69	3.77	3.86	3.94	4.02	4.11	4.19	4.27	4.35	4.44	4.52	4.60	4.69	4.77
46	2.73	2.81	2.90	2.98	3.06	3.15	3.23	3.31	3.39	3.48	3.56	3.64	3.73	3.81	3.89	3.97	4.06	4.14	4.23	4.31	4.39	4.47	4.55	4.64	4.72
48	2.68	2.77	2.85	2.93	3.01	3.10	3.18	3.26	3.35	3.43	3.51	3.59	3.68	3.76	3.84	3.93	4.01	4.09	4.17	4.25	4.34	4.42	4.50	4.59	4.67
50	2.63	2.72	2.80	2.88	2.97	3.05	3.13	3.21	3.30	3.38	3.46	3.55	3.63	3.71	3.79	3.88	3.96	4.04	4.12	4.21	4.29	4.37	4.46	4.54	4.62
52	2.59	2.67	2.75	2.83	2.92	3.00	3.08	3.17	3.25	3.33	3.41	3.50	3.58	3.66	3.74	3.83	3.91	3.99	4.08	4.16	4.24	4.32	4.41	4.49	4.57
54	2.54	2.62	2.70	2.79	2.87	2.95	3.03	3.12	3.20	3.28	3.36	3.45	3.53	3.61	3.70	3.78	3.86	3.94	4.03	4.11	4.19	4.28	4.36	4.44	4.52
56	2.49	2.57	2.65	2.74	2.82	2.90	2.98	3.07	3.15	3.23	3.32	3.40	3.48	3.56	3.65	3.73	3.81	3.90	3.98	4.06	4.14	4.23	4.31	4.39	4.48
58	2.44	2.52	2.60	2.69	2.77	2.85	2.94	3.02	3.10	3.18	3.27	3.35	3.43	3.52	3.60	3.68	3.76	3.85	3.93	4.01	4.10	4.18	4.26	4.34	4.43
60	2.39	2.47	2.55	2.64	2.72	2.80	2.89	2.97	3.05	3.14	3.22	3.30	3.38	3.47	3.55	3.63	3.72	3.80	3.88	3.96	4.05	4.13	4.21	4.29	4.38
62	2.34	2.42	2.51	2.59	2.67	2.76	2.84	2.92	3.00	3.09	3.17	3.25	3.34	3.42	3.50	3.58	3.67	3.75	3.83	3.91	4.00	4.08	4.16	4.25	4.33
64	2.29	2.38	2.46	2.54	2.62	2.71	2.79	2.87	2.96	3.04	3.12	3.20	3.29	3.37	3.45	3.53	3.62	3.70	3.78	3.87	3.95	4.03	4.11	4.20	4.28
66	2.24	2.33	2.41	2.49	2.58	2.66	2.74	2.82	2.91	2.99	3.07	3.15	3.24	3.32	3.40	3.49	3.57	3.65	3.73	3.82	3.90	3.98	4.07	4.15	4.23
68	2.20	2.28	2.36	2.44	2.53	2.61	2.69	2.77	2.86	2.94	3.02	3.11	3.19	3.27	3.35	3.44	3.52	3.60	3.69	3.77	3.85	3.93	4.02	4.10	4.18
70	2.15	2.23	2.31	2.39	2.48	2.56	2.64	2.73	2.81	2.89	2.97	3.06	3.14	3.22	3.31	3.39	3.47	3.55	3.64	3.72	3.80	3.89	3.97	4.05	4.13
72	2.10	2.18	2.26	2.35	2.43	2.51	2.59	2.68	2.76	2.84	2.93	3.01	3.09	3.17	3.26	3.34	3.42	3.51	3.59	3.67	3.75	3.84	3.92	4.00	4.08
74	2.05	2.13	2.21	2.30	2.38	2.46	2.55	2.63	2.71	2.79	2.88	2.96	3.04	3.13	3.21	3.29	3.37	3.46	3.54	3.62	3.70	3.79	3.87	3.95	4.04

*FEV_1 in liters = 0.0414 H − 0.0244 A − 2.190. R^2 = 0.64; SEE = 0.486; 95% confidence interval = 0.842. Definitions of abbreviations: R^2 = coefficient of determination; SEE = standard error of estimate; H = height in cm; A = age in years. BTPS = body temperature, ambient pressure, and saturated with water vapor at these conditions. Adapted from Crapo et al.[1]

Table 5-4b Predicted Lower Limit of Normal Forced Expiratory Volume in the First Second (FEV_1) for Men*

Age	Height (cm) 146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	2.578	2.658	2.738	2.818	2.908	2.988	3.068	3.148	3.238	3.318	3.398	3.488	3.568	3.648	3.728	3.818	3.898	3.978	4.068	4.148	4.228	4.308	4.398	4.478	4.558
20	2.528	2.608	2.688	2.768	2.858	2.938	3.018	3.108	3.188	3.268	3.348	3.438	3.518	3.598	3.688	3.768	3.848	3.928	4.018	4.098	4.178	4.268	4.348	4.428	4.508
22	2.478	2.558	2.638	2.728	2.808	2.888	2.968	3.058	3.138	3.218	3.308	3.388	3.468	3.548	3.638	3.718	3.798	3.888	3.968	4.048	4.128	4.208	4.298	4.378	4.458
24	2.428	2.508	2.588	2.678	2.758	2.838	2.928	3.008	3.088	3.168	3.258	3.338	3.418	3.508	3.588	3.668	3.748	3.838	3.918	3.998	4.078	4.168	4.248	4.328	4.418
26	2.378	2.458	2.548	2.628	2.708	2.788	2.878	2.958	3.038	3.128	3.208	3.288	3.368	3.458	3.538	3.618	3.698	3.788	3.868	3.948	4.038	4.058	4.198	4.278	4.368
28	2.328	2.408	2.498	2.578	2.658	2.748	2.828	2.908	2.988	3.078	3.158	3.238	3.318	3.408	3.488	3.568	3.658	3.738	3.818	3.898	3.988	4.068	4.148	4.238	4.318
30	2.278	2.368	2.448	2.528	2.608	2.698	2.778	2.858	2.938	3.028	3.108	3.188	3.278	3.358	3.438	3.518	3.608	3.688	3.768	3.858	3.938	4.018	4.098	4.188	4.268
32	2.228	2.318	2.398	2.478	2.558	2.648	2.728	2.808	2.898	2.978	3.058	3.138	3.228	3.308	3.388	3.478	3.558	3.638	3.718	3.808	3.888	3.968	4.058	4.138	4.218
34	2.178	2.268	2.348	2.428	2.518	2.598	2.678	2.758	2.848	2.928	3.008	3.098	3.178	3.258	3.338	3.428	3.508	3.588	3.678	3.758	3.838	3.918	4.008	4.088	4.168
36	2.138	2.218	2.298	2.378	2.468	2.548	2.628	2.718	2.798	2.878	2.958	3.048	3.128	3.208	3.298	3.378	3.458	3.538	3.628	3.708	3.788	3.868	3.958	4.038	4.118
38	2.088	2.168	2.248	2.338	2.418	2.498	2.578	2.668	2.748	2.828	2.918	2.998	3.078	3.158	3.248	3.328	3.408	3.488	3.578	3.658	3.738	3.828	3.908	3.988	4.068
40	2.038	2.118	2.198	2.288	2.368	2.448	2.538	2.618	2.698	2.778	2.868	2.948	3.028	3.108	3.198	3.278	3.358	3.448	3.528	3.608	3.688	3.778	3.858	3.938	4.028
42	1.988	2.068	2.158	2.238	2.318	2.398	2.488	2.568	2.648	2.728	2.818	2.898	2.978	3.068	3.148	3.228	3.308	3.398	3.478	3.558	3.648	3.728	3.808	3.888	3.978
44	1.938	2.018	2.108	2.188	2.268	2.348	2.438	2.518	2.598	2.688	2.768	2.848	2.928	3.018	3.098	3.178	3.268	3.348	3.428	3.508	3.598	3.678	3.758	3.848	3.928
46	1.888	1.968	2.058	2.138	2.218	2.308	2.388	2.468	2.548	2.638	2.718	2.798	2.888	2.968	3.048	3.128	3.218	3.298	3.378	3.468	3.548	3.628	3.708	3.798	3.878
48	1.838	1.928	2.008	2.088	2.168	2.258	2.338	2.418	2.508	2.588	2.668	2.748	2.838	2.918	2.998	3.088	3.168	3.248	3.328	3.408	3.498	3.578	3.658	3.748	3.828
50	1.788	1.878	1.958	2.038	2.128	2.208	2.288	2.368	2.458	2.538	2.618	2.708	2.788	2.868	2.948	3.038	3.118	3.198	3.278	3.368	3.448	3.528	3.618	3.698	3.778
52	1.748	1.828	1.908	1.988	2.078	2.158	2.238	2.328	2.408	2.488	2.568	2.658	2.738	2.818	2.898	2.988	3.068	3.148	3.238	3.318	3.398	3.478	3.568	3.648	3.728
54	1.698	1.778	1.858	1.948	2.028	2.108	2.188	2.278	2.358	2.438	2.518	2.608	2.688	2.768	2.858	2.938	3.018	3.098	3.188	3.268	3.348	3.438	3.518	3.598	3.678
56	1.648	1.728	1.808	1.898	1.978	2.058	2.138	2.228	2.308	2.388	2.478	2.558	2.638	2.718	2.808	2.888	2.968	3.058	3.138	3.218	3.298	3.388	3.468	3.548	3.638
58	1.598	1.678	1.758	1.848	1.928	2.008	2.098	2.178	2.258	2.338	2.428	2.508	2.588	2.678	2.758	2.838	2.918	3.008	3.088	3.168	3.258	3.338	3.418	3.498	3.588
60	1.548	1.628	1.708	1.798	1.878	1.958	2.048	2.128	2.208	2.298	2.378	2.458	2.538	2.628	2.708	2.788	2.878	2.958	3.038	3.118	3.208	3.288	3.368	3.448	3.538
62	1.498	1.578	1.668	1.748	1.828	1.918	1.998	2.078	2.158	2.248	2.328	2.408	2.498	2.578	2.658	2.738	2.828	2.908	2.988	3.068	3.158	3.238	3.318	3.408	3.488
64	1.448	1.538	1.618	1.698	1.778	1.868	1.948	2.028	2.118	2.198	2.278	2.358	2.448	2.528	2.608	2.688	2.778	2.858	2.938	3.028	3.108	3.188	3.268	3.358	3.438
66	1.398	1.488	1.568	1.648	1.738	1.818	1.898	1.978	2.068	2.148	2.228	2.308	2.398	2.478	2.558	2.648	2.728	2.808	2.888	2.978	3.058	3.138	3.228	3.308	3.388
68	1.358	1.438	1.518	1.598	1.688	1.768	1.848	1.928	2.018	2.098	2.178	2.268	2.348	2.428	2.508	2.598	2.678	2.758	2.848	2.928	3.008	3.088	3.178	3.258	3.338
70	1.308	1.388	1.468	1.548	1.638	1.718	1.798	1.888	1.968	2.048	2.128	2.218	2.298	2.378	2.468	2.548	2.628	2.708	2.798	2.878	2.958	3.048	3.128	3.208	3.288
72	1.258	1.338	1.418	1.508	1.588	1.668	1.748	1.838	1.918	1.998	2.088	2.168	2.248	2.328	2.418	2.498	2.578	2.668	2.748	2.828	2.908	2.998	3.078	3.158	3.238
74	1.208	1.288	1.368	1.458	1.538	1.618	1.708	1.788	1.868	1.948	2.038	2.118	2.198	2.288	2.368	2.448	2.528	2.618	2.698	2.778	2.858	2.948	3.028	3.108	3.198

*FEV_1 values are given in liters. The values listed here reflect the FEV_1 as listed in Table 5—4a minus 0.842 L (95% confidence interval). Adapted from Crapo et al.[1]

Table 5-5a Predicted Normal Forced Expiratory Volume in the First Second (FEV_1) in Liters for Women*

Age	Height (cm)																								
	146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	2.96	3.02	3.09	3.16	3.23	3.30	3.37	3.43	3.50	3.57	3.64	3.71	3.78	3.85	3.91	3.98	4.05	4.12	4.19	4.26	4.32	4.39	4.46	4.53	4.60
20	2.91	2.97	3.04	3.11	3.18	3.25	3.32	3.38	3.45	3.52	3.59	3.66	3.73	3.79	3.86	3.93	4.00	4.07	4.14	4.20	4.27	4.34	4.41	4.48	4.55
22	2.85	2.92	2.99	3.06	3.13	3.20	3.26	3.33	3.40	3.47	3.54	3.61	3.67	3.74	3.81	3.88	3.95	4.02	4.09	4.15	4.22	4.29	4.36	4.43	4.50
24	2.80	2.87	2.94	3.01	3.08	3.15	3.21	3.28	3.35	3.42	3.49	3.56	3.62	3.69	3.76	3.83	3.90	3.97	4.03	4.10	4.17	4.24	4.31	4.38	4.44
26	2.75	2.82	2.89	2.96	3.03	3.09	3.16	3.23	3.30	3.37	3.44	3.50	3.57	3.64	3.71	3.78	3.85	3.91	3.98	4.05	4.12	4.19	4.26	4.33	4.39
28	2.70	2.77	2.84	2.91	2.97	3.04	3.11	3.18	3.25	3.32	3.39	3.45	3.52	3.59	3.66	3.73	3.80	3.86	3.93	4.00	4.07	4.14	4.21	4.27	4.34
30	2.65	2.72	2.79	2.86	2.92	2.99	3.06	3.13	3.20	3.27	3.33	3.40	3.47	3.54	3.61	3.68	3.74	3.81	3.88	3.95	4.02	4.09	4.15	4.22	4.29
32	2.60	2.67	2.74	2.80	2.87	2.94	3.01	3.08	3.15	3.21	3.28	3.35	3.42	3.49	3.56	3.63	3.69	3.76	3.83	3.90	3.97	4.04	4.10	4.17	4.24
34	2.55	2.62	2.68	2.75	2.82	2.89	2.96	3.03	3.10	3.16	3.23	3.30	3.37	3.44	3.51	3.57	3.64	3.71	3.78	3.85	3.92	3.98	4.05	4.12	4.19
36	2.50	2.57	2.63	2.70	2.77	2.84	2.91	2.98	3.04	3.11	3.18	3.25	3.32	3.39	3.45	3.52	3.59	3.66	3.73	3.80	3.87	3.93	4.00	4.07	4.14
38	2.45	2.51	2.58	2.65	2.72	2.79	2.86	2.92	2.99	3.06	3.13	3.20	3.27	3.34	3.40	3.47	3.54	3.61	3.68	3.75	3.81	3.88	3.95	4.02	4.09
40	2.40	2.46	2.53	2.60	2.67	2.74	2.81	2.87	2.94	3.01	3.08	3.15	3.22	3.28	3.35	3.42	3.49	3.56	3.63	3.69	3.76	3.83	3.90	[illegible]	4.0[illegible]
42	2.34	2.41	2.48	2.55	2.62	2.69	2.75	2.82	2.89	2.96	3.03	3.10	3.17	3.23	3.30	3.37	3.44	3.51	3.58	3.64	3.71	3.78	3.85	[illegible]	3.9[illegible]
44	2.29	2.36	2.43	2.50	2.57	2.64	2.70	2.77	2.84	2.91	2.98	3.05	3.11	3.18	3.25	3.32	3.39	3.46	3.52	3.59	3.66	3.73	3.80	[illegible]	3.9[illegible]
46	2.24	2.31	2.38	2.45	2.52	2.58	2.65	2.72	2.79	2.86	2.93	2.99	3.06	3.13	3.20	3.27	3.34	3.41	3.47	3.54	3.61	3.68	3.75	[illegible]	3.8[illegible]
48	2.19	2.26	2.33	2.40	2.46	2.53	2.60	2.67	2.74	2.81	2.88	2.94	3.01	3.08	3.15	3.22	3.28	3.35	3.42	3.49	3.56	3.62	3.70	[illegible]	3.83
50	2.14	2.21	2.28	2.35	2.41	2.48	2.55	2.62	2.69	2.76	2.82	2.89	2.96	3.03	3.10	3.17	3.23	3.30	3.37	3.44	3.51	3.58	3.65	[illegible]	3.78
52	2.09	2.16	2.23	2.29	2.36	2.43	2.50	2.57	2.64	2.70	2.77	2.84	2.91	2.98	3.05	3.12	3.18	3.25	3.32	3.39	3.46	3.53	3.59	3.66	3.73
54	2.04	2.11	2.18	2.24	2.31	2.38	2.45	2.52	2.59	2.65	2.72	2.79	3.86	2.93	3.00	3.06	3.13	3.20	3.27	3.34	3.41	3.47	3.54	3.61	3.68
56	1.99	2.06	2.12	2.19	2.26	2.33	2.40	2.47	2.53	2.60	2.67	2.74	2.81	2.88	2.94	3.01	3.08	3.15	3.22	3.29	3.36	3.42	3.49	3.56	3.63
58	1.94	2.00	2.07	2.14	2.21	2.28	2.35	2.42	2.48	2.55	2.62	2.69	2.76	2.83	2.89	2.96	3.03	3.10	3.17	3.24	3.30	3.37	3.44	3.51	3.58
60	1.89	1.95	2.02	2.09	2.16	2.23	2.30	2.36	2.43	2.50	2.57	2.64	2.71	2.77	2.84	2.91	2.98	3.05	3.12	3.18	3.25	3.32	3.39	3.46	3.53
62	1.83	1.90	1.97	2.04	2.11	2.18	2.24	2.31	2.38	2.45	2.52	2.59	2.66	2.72	2.79	2.86	2.93	3.00	3.07	3.13	3.20	3.27	3.34	3.41	3.48
64	1.78	1.85	1.92	1.99	2.06	2.13	2.19	2.26	2.33	2.40	2.47	2.54	2.60	2.67	2.74	2.81	2.88	2.95	3.01	3.08	3.15	3.22	3.29	3.36	3.42
66	1.73	1.80	1.87	1.94	2.01	2.07	2.14	2.21	2.28	2.35	2.42	2.48	2.55	2.62	2.69	2.76	2.83	2.90	2.96	3.03	3.10	3.17	3.24	3.31	3.37
68	1.68	1.75	1.82	1.89	1.95	2.02	2.09	2.16	2.23	2.30	2.37	2.43	2.50	2.57	2.64	2.71	2.78	2.84	2.91	2.98	3.05	3.12	3.19	3.25	3.32
70	1.63	1.70	1.77	1.84	1.90	1.97	2.04	2.11	2.18	2.25	2.31	2.38	2.45	2.52	2.59	2.66	2.72	2.79	2.86	2.93	3.00	3.07	3.14	3.20	3.27
72	1.58	1.65	1.72	1.78	1.85	1.92	1.99	2.06	2.13	2.19	2.26	2.33	2.40	2.47	2.54	2.61	2.67	2.74	2.81	2.88	2.95	3.02	3.08	3.15	3.22
74	1.53	1.60	1.67	1.73	1.80	1.87	1.94	2.01	2.08	2.14	2.21	2.28	2.35	2.42	2.49	2.55	2.62	2.69	2.76	2.83	2.90	2.96	3.03	3.10	3.17

*FEV_1 in liters = 0.0342 H − 0.0225 A − 1.578. R^2 = 0.80; SEE = 0.326; 95% confidence interval = 0.561. Definitions of abbreviations: R^2 = coefficient of determination; SEE = standard error of estimate; H = height in cm; A = age in years. BTPS = body temperature, ambient pressure, and saturated with water vapor at these conditions. Adapted from Crapo et al.[3]

Table 5-5b Predicted Lower Limit of Normal Forced Expiratory Volume in the First Second (FEV_1) for Women*

Age	Height (cm)																								
	146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	2.399	2.459	2.529	2.599	2.669	2.739	2.809	2.869	2.939	3.009	3.079	3.149	3.219	3.289	3.349	3.419	3.489	3.559	3.629	3.699	3.759	3.829	3.899	3.969	4.039
20	2.349	2.409	2.479	2.549	2.619	2.689	2.759	2.819	2.889	2.959	3.029	3.099	3.169	3.229	3.299	3.369	3.439	3.509	3.579	3.639	3.709	3.779	3.849	3.919	3.989
22	2.289	2.359	2.429	2.499	2.569	2.639	2.699	2.769	2.839	2.909	2.979	3.049	3.109	3.179	3.249	3.319	3.389	3.459	3.529	3.589	3.659	3.729	3.799	3.869	3.939
24	2.239	2.309	2.379	2.449	2.519	2.589	2.649	2.719	2.789	2.859	2.929	2.999	3.059	3.129	3.199	3.269	3.339	3.409	3.469	3.539	3.609	3.679	3.749	3.819	3.879
26	2.189	2.259	2.329	2.399	2.469	2.529	2.599	2.669	2.739	2.809	2.879	2.939	3.009	3.079	3.149	3.219	3.289	3.349	3.419	3.489	3.559	3.629	3.699	3.769	3.829
28	2.139	2.209	2.279	2.349	2.409	2.479	2.549	2.619	2.689	2.759	2.829	2.889	2.959	3.029	3.099	3.169	3.239	3.299	3.369	3.439	3.509	3.579	3.649	3.709	3.779
30	2.089	2.159	2.229	2.299	2.359	2.429	2.499	2.569	2.639	2.709	2.769	2.839	2.909	2.979	3.049	3.119	3.179	3.249	3.319	3.389	3.459	3.529	3.589	3.659	3.729
32	2.039	2.109	2.179	2.239	2.309	2.379	2.449	2.519	2.589	2.649	2.719	2.789	2.859	2.929	2.999	3.069	3.129	3.199	3.269	3.339	3.409	3.479	3.539	3.609	3.679
34	1.989	2.059	2.119	2.189	2.259	2.329	2.399	2.469	2.539	2.599	2.669	2.739	2.809	2.879	2.949	3.009	3.079	3.149	3.219	3.289	3.359	3.419	3.489	3.559	3.629
36	1.939	2.009	2.069	2.139	2.209	2.279	2.349	2.419	2.479	2.549	2.619	2.689	2.759	2.829	2.889	2.959	3.029	3.099	3.169	3.239	3.309	3.369	3.439	3.509	3.579
38	1.889	1.949	2.019	2.089	2.159	2.229	2.299	2.359	2.429	2.499	2.569	2.639	2.709	2.779	2.839	2.909	2.979	3.049	3.119	3.189	3.249	3.319	3.389	3.459	3.529
40	1.839	1.899	1.969	2.039	2.109	2.179	2.249	2.309	2.379	2.449	2.519	2.589	2.659	2.719	2.789	2.859	2.929	2.999	3.069	3.129	3.199	3.269	3.339	3.409	3.479
42	1.779	1.849	1.919	1.989	2.059	2.129	2.189	2.259	2.329	2.399	2.469	2.539	2.609	2.669	2.739	2.809	2.879	2.949	3.019	3.079	3.149	3.219	3.289	3.359	3.429
44	1.729	1.799	1.869	1.939	2.009	2.079	2.139	2.209	2.279	2.349	2.419	2.489	2.549	2.619	2.689	2.759	2.829	2.899	2.959	3.029	3.099	3.169	3.239	3.309	3.369
46	1.679	1.749	1.819	1.889	1.959	2.019	2.089	2.159	2.229	2.299	2.369	2.429	2.499	2.569	2.639	2.709	2.779	2.849	2.909	2.979	3.049	3.119	3.189	3.259	3.319
48	1.629	1.699	1.769	1.839	1.899	1.969	2.039	2.109	2.179	2.249	2.319	2.379	2.449	2.519	2.589	2.659	2.729	2.789	2.859	2.929	2.999	3.069	3.139	3.199	3.269
50	1.579	1.649	1.719	1.789	1.849	1.919	1.989	2.059	2.129	2.199	2.259	2.329	2.399	2.469	2.539	2.609	2.669	2.739	2.809	2.879	2.949	3.019	3.089	3.149	3.219
52	1.529	1.599	1.669	1.729	1.799	1.869	1.939	2.009	2.079	2.139	2.209	2.279	2.349	2.419	2.489	2.559	2.619	2.689	2.759	2.829	2.899	2.969	3.029	3.099	3.169
54	1.479	1.549	1.619	1.679	1.749	1.819	1.889	1.959	2.029	2.089	2.159	2.229	3.299	2.369	2.439	2.499	2.569	2.639	2.709	2.779	2.849	2.909	2.979	3.049	3.119
56	1.429	1.499	1.559	1.629	1.699	1.769	1.839	1.909	1.969	2.039	2.109	2.179	2.249	2.319	2.379	2.449	2.519	2.589	2.659	2.729	2.799	2.859	2.929	2.999	3.069
58	1.379	1.439	1.509	1.579	1.649	1.719	1.789	1.859	1.919	1.989	2.059	2.129	2.199	2.269	2.329	2.399	2.469	2.539	2.609	2.679	2.739	2.809	2.879	2.949	3.019
60	1.329	1.389	1.459	1.529	1.599	1.669	1.739	1.799	1.869	1.939	2.009	2.079	2.149	2.209	2.279	2.349	2.419	2.489	2.559	2.619	2.689	2.759	2.829	2.899	2.969
62	1.269	1.339	1.409	1.479	1.549	1.619	1.679	1.749	1.819	1.889	1.959	2.029	2.099	2.159	2.229	2.299	2.369	2.439	2.509	2.569	2.639	2.709	2.779	2.849	2.919
64	1.219	1.289	1.359	1.429	1.499	1.569	1.629	1.699	1.769	1.839	1.909	1.979	2.039	2.109	2.179	2.249	2.319	2.389	2.449	2.519	2.589	2.659	2.729	2.799	2.859
66	1.169	1.239	1.309	1.379	1.449	1.509	1.579	1.649	1.719	1.789	1.859	1.919	1.989	2.059	2.129	2.199	2.269	2.339	2.399	2.469	2.539	2.609	2.679	2.749	2.809
68	1.119	1.189	1.259	1.329	1.389	1.459	1.529	1.599	1.669	1.739	1.809	1.869	1.939	2.009	2.079	2.149	2.219	2.279	2.349	2.419	2.489	2.559	2.629	2.689	2.759
70	1.069	1.139	1.209	1.279	1.339	1.409	1.479	1.549	1.619	1.689	1.749	1.819	1.889	1.959	2.029	2.099	2.159	2.229	2.299	2.369	2.439	2.509	2.579	2.639	2.709
72	1.019	1.089	1.159	1.219	1.289	1.359	1.429	1.499	1.569	1.629	1.699	1.769	1.839	1.909	1.979	2.049	2.109	2.179	2.249	2.319	2.389	2.459	2.519	2.589	2.659
74	0.969	1.039	1.109	1.169	1.239	1.309	1.379	1.449	1.519	1.579	1.649	1.719	1.789	1.859	1.929	1.989	2.059	2.129	2.199	2.269	2.339	2.399	2.469	2.539	2.609

*FEV_1 values are given in liters. The values listed here reflect the FEV_1 as listed in Table 5–5a minus 0.561 L (95% confidence interval). Adapted from Crapo et al.[3]

Table 5-6a Predicted Normal Diffusing Capacity for Carbon Monoxide (Dco) for Men (STPD)*

Age	Height (cm)																								
	146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	29.8	30.6	31.4	32.2	33.1	33.9	34.7	35.5	36.3	37.1	38.0	38.8	39.6	40.4	41.2	42.1	42.9	43.7	44.5	45.4	46.2	47.0	47.8	48.6	49.4
20	29.3	30.2	31.0	31.8	32.6	33.4	34.3	35.1	35.9	36.7	37.5	38.4	39.2	40.0	40.8	41.6	42.5	43.3	44.1	44.9	45.7	46.6	47.4	48.2	49.0
22	28.9	29.7	30.6	31.4	32.2	33.0	33.8	34.7	35.5	36.3	37.1	37.9	38.8	39.6	40.4	41.2	42.0	42.9	43.7	44.5	45.3	46.1	47.0	47.8	48.6
24	28.5	29.3	30.1	31.0	31.8	32.6	33.4	34.2	35.1	35.9	36.7	37.5	38.3	39.2	40.0	40.8	41.6	42.4	43.3	44.1	44.9	45.7	46.5	47.4	48.2
26	28.1	28.9	29.7	30.5	31.4	32.2	33.0	33.8	34.6	35.5	36.3	37.1	37.9	38.7	39.6	40.4	41.2	42.0	42.8	43.7	44.5	45.3	46.1	46.9	47.8
28	27.7	28.5	29.3	30.1	30.9	31.8	32.6	33.4	34.2	35.0	35.9	36.7	37.5	38.3	39.1	40.0	40.8	41.6	42.4	43.2	44.1	44.9	45.7	46.5	47.3
30	27.2	28.1	28.9	29.7	30.5	31.3	32.2	33.0	33.8	34.6	35.4	36.3	37.1	37.9	38.7	39.6	40.4	41.2	42.0	42.8	43.6	44.5	45.3	46.1	46.9
32	26.8	27.6	28.5	29.3	30.1	30.9	31.7	32.6	33.4	34.2	35.0	35.8	36.7	37.5	38.3	39.1	39.9	40.8	41.6	42.4	43.2	44.1	44.9	45.7	46.5
34	26.4	27.2	28.1	28.9	29.7	30.5	31.3	32.1	33.0	33.8	34.6	35.4	36.2	37.1	37.9	38.7	39.5	40.4	41.2	42.0	42.8	43.6	44.4	45.3	46.1
36	26.0	26.8	27.6	28.4	29.3	30.1	30.9	31.7	32.5	33.4	34.2	35.0	35.8	36.6	37.5	38.3	39.1	39.9	40.7	41.6	42.4	43.2	44.0	44.8	45.7
38	25.6	26.4	27.2	28.0	28.8	29.7	30.5	31.3	32.1	32.9	33.8	34.6	35.4	36.2	37.0	37.9	38.7	39.5	40.3	41.1	42.0	42.8	43.6	44.4	45.2
40	25.1	26.0	26.8	27.6	28.4	29.2	30.1	30.9	31.7	32.5	33.3	34.2	35.0	35.8	36.6	37.4	38.3	39.1	39.9	40.7	41.5	42.4	43.2	44.0	44.8
42	24.7	25.5	26.4	27.2	28.0	28.8	29.6	30.5	31.3	32.1	32.9	33.7	34.6	35.4	36.2	37.0	37.8	38.7	39.5	40.3	41.1	41.9	42.8	43.6	44.4
44	24.3	25.1	25.9	26.8	27.6	28.4	29.2	30.0	30.9	31.7	32.5	33.3	34.1	35.0	35.8	36.6	37.4	38.2	39.1	39.9	40.7	41.5	42.3	43.2	44.0
46	23.9	24.7	25.5	26.3	27.2	28.0	28.8	29.6	30.4	31.3	32.1	32.9	33.7	34.6	35.4	36.2	37.0	37.8	38.6	39.5	40.3	41.1	41.9	[illegible]	[illegible]
48	23.5	24.3	25.1	25.9	26.7	27.6	28.4	29.2	30.0	30.8	31.7	32.5	33.3	34.1	34.9	35.8	36.6	37.4	38.2	39.1	39.9	40.7	41.5	42.3	43.1
50	23.1	23.9	24.7	25.5	26.3	27.1	28.0	28.8	29.6	30.4	31.2	32.1	32.9	33.7	34.5	35.4	36.2	37.0	37.8	38.6	39.4	40.3	41.1	41.9	42.7
52	22.6	23.4	24.3	25.1	25.9	26.7	27.6	28.4	29.2	30.0	30.8	31.6	32.5	33.3	34.1	34.9	35.7	36.6	37.4	38.2	39.0	39.9	40.7	41.6	42.3
54	22.2	23.0	23.8	24.7	25.5	26.3	27.1	27.9	28.8	29.6	30.4	31.2	32.0	32.9	33.7	34.5	35.3	36.1	37.0	37.8	38.6	39.4	40.2	41.1	41.9
56	21.8	22.6	23.4	24.2	25.1	25.9	26.7	27.5	28.3	29.2	30.0	30.8	31.6	32.4	33.3	34.1	34.9	35.7	36.5	37.4	38.2	39.0	39.8	40.6	41.5
58	21.4	22.2	23.0	23.8	24.6	25.5	26.3	27.1	27.9	28.7	29.6	30.4	31.2	32.0	32.8	33.7	34.5	35.3	36.1	36.9	37.8	38.6	39.4	40.2	41.0
60	20.9	21.8	22.6	23.4	24.2	25.0	25.9	26.7	27.5	28.3	29.1	30.0	30.8	31.6	32.4	33.2	34.1	34.9	35.7	36.5	37.3	38.2	39.0	39.8	40.6
62	20.5	21.3	22.2	23.0	23.8	24.6	25.4	26.3	27.1	27.9	28.7	29.5	30.4	31.2	32.0	32.8	33.6	34.5	35.3	36.1	36.9	37.7	38.6	39.4	40.2
64	20.1	20.9	21.7	22.6	23.4	24.2	25.0	25.8	26.7	27.5	28.3	29.1	29.9	30.8	31.6	32.4	33.2	34.1	34.9	35.7	36.5	37.3	38.1	39.0	39.8
66	19.7	20.5	21.3	22.1	23.0	23.8	24.6	25.4	26.2	27.1	27.9	28.7	29.5	30.4	31.2	32.0	32.8	33.6	34.4	35.3	36.1	36.9	37.7	38.6	39.4
68	19.3	20.1	20.9	21.7	22.6	23.4	24.2	25.0	25.8	26.6	27.5	28.3	29.1	29.9	30.7	31.6	32.4	38.2	34.0	34.9	35.7	36.5	37.3	38.1	38.9
70	18.8	19.7	20.5	21.3	22.1	22.9	23.8	24.6	25.4	26.2	27.0	27.9	28.7	29.5	30.3	31.1	32.0	32.8	33.6	34.4	35.2	36.1	36.9	37.7	38.5
72	18.4	19.2	20.1	20.9	21.7	22.5	23.3	24.2	25.0	25.8	26.6	27.4	28.3	29.1	29.9	30.7	31.5	32.4	33.2	34.0	34.8	35.6	36.5	37.3	38.1
74	18.0	18.8	19.6	20.5	21.3	22.1	22.9	23.7	24.6	25.4	26.2	27.0	27.8	28.7	29.5	30.3	31.1	31.9	32.8	33.6	34.4	35.2	36.0	36.9	37.7

Dco in mL/min/mm Hg = 0.410 H − 0.210 A − 26.31. R^2 = 0.68; SEE = 4.82; 95% confidence interval = 8.2. Definitions of abbreviations: R^2 = coefficient of determination; SEE = standard error of estimate; H = height in cm; A = age in years. STPD = temperature 0°C, pressure 760 mm Hg, and dry (0 water vapor). The regression analysis has been normalized to a standard hemoglobin of 146 g/L by means of Cotes' modification of the relationship described by Roughton and Forster. Adapted from Crapo and Morris.

Table 5-6b Predicted Lower Limit of Normal Diffusing Capacity for Carbon Monoxide (Dco) for Men*

Age	Height (cm)																								
	146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	21.6	22.4	23.2	24.0	24.9	25.7	26.5	27.3	28.1	28.9	29.8	30.6	31.4	32.2	33.0	33.9	34.7	35.5	36.3	37.2	38.0	38.8	39.6	40.4	41.2
20	21.1	22.0	22.8	23.6	24.4	25.2	26.1	26.9	27.7	28.5	29.3	30.2	31.0	31.8	32.6	33.4	34.3	35.1	35.9	36.7	37.5	38.4	39.2	40.0	40.8
22	20.7	21.5	22.4	23.2	24.0	24.8	25.6	26.5	27.3	28.1	28.9	29.7	30.6	31.4	32.2	33.0	33.8	34.7	35.5	36.3	37.1	37.9	38.8	39.6	40.4
24	20.3	21.1	21.9	22.8	23.6	24.4	25.2	26.0	26.9	27.7	28.5	29.3	30.1	31.0	31.8	32.6	33.4	34.2	35.1	35.9	36.7	37.5	38.3	39.2	40.0
26	19.9	20.7	21.5	22.3	23.2	24.0	24.8	25.6	26.4	27.3	28.1	28.9	29.7	30.5	31.4	32.2	33.0	33.8	34.6	35.5	36.3	37.1	37.9	38.7	39.6
28	19.5	20.3	21.1	21.9	22.7	23.6	24.4	25.2	26.0	26.8	27.7	28.5	29.3	30.1	30.9	31.8	32.6	33.4	34.2	35.0	35.9	36.7	37.5	38.3	39.1
30	19.0	19.9	20.7	21.5	22.3	23.1	24.0	24.8	25.6	26.4	27.2	28.1	28.9	29.7	30.5	31.4	32.2	33.0	33.8	34.6	35.4	36.3	37.1	37.9	38.7
32	18.6	19.4	20.3	21.1	21.9	22.7	23.5	24.4	25.2	26.0	26.8	27.6	28.5	29.3	30.1	30.9	31.7	32.6	33.4	34.2	35.0	35.9	36.7	37.5	38.3
34	18.2	19.0	19.9	20.7	21.5	22.3	23.1	23.9	24.8	25.6	26.4	27.2	28.0	28.9	29.7	30.5	31.3	32.2	33.0	33.8	34.6	35.4	36.2	37.1	37.9
36	17.8	18.6	19.4	20.2	21.1	21.9	22.7	23.5	24.3	25.2	26.0	26.8	27.6	28.4	29.3	30.1	30.9	31.7	32.5	33.4	34.2	35.0	35.8	36.6	37.5
38	17.4	18.2	19.0	19.8	20.6	21.5	22.3	23.1	23.9	24.7	25.6	26.4	27.2	28.0	28.8	29.7	30.5	31.3	37.1	32.9	33.8	34.6	35.4	36.2	37.0
40	16.9	17.8	18.6	19.4	20.2	21.0	21.9	22.7	23.5	24.3	25.1	26.0	26.8	27.6	28.4	29.2	30.1	30.9	31.7	32.5	33.3	34.2	35.0	35.8	36.6
42	16.5	17.3	18.2	19.0	19.8	20.6	21.4	22.3	23.1	23.9	24.7	25.5	26.4	27.2	28.0	28.8	29.6	30.5	31.3	32.1	32.9	33.7	34.6	35.4	36.2
44	16.1	16.9	17.7	18.6	19.4	20.2	21.0	21.8	22.7	23.5	24.3	25.1	25.9	26.8	27.6	28.4	29.2	30.0	30.9	31.7	32.5	33.3	34.1	35.0	35.8
46	15.7	16.5	17.3	18.1	19.0	19.8	20.6	21.4	22.2	23.1	23.9	24.7	25.5	26.4	27.2	28.0	28.8	29.6	30.4	31.3	32.1	32.9	33.7	34.5	35.4
48	15.3	16.1	16.9	17.7	18.5	19.4	20.2	21.0	21.8	22.6	23.5	24.3	25.1	25.9	26.7	27.6	28.4	29.2	30.0	30.9	31.7	32.5	33.3	34.1	34.9
50	14.9	15.7	16.5	17.3	18.1	18.9	19.8	20.6	21.4	22.2	23.0	23.9	24.7	25.5	26.3	27.2	28.0	28.8	29.6	30.4	31.2	32.1	32.9	33.7	34.5
52	14.4	15.2	16.1	16.9	17.7	18.5	19.4	20.2	21.0	21.8	22.6	23.4	24.3	25.1	25.9	26.7	27.5	28.4	29.2	30.0	30.8	31.7	32.5	33.4	34.1
54	14.0	14.8	15.6	16.5	17.3	18.1	18.9	19.7	20.6	21.4	22.2	23.0	23.8	24.7	25.5	26.3	27.1	27.9	28.8	29.6	30.4	31.2	32.0	32.9	33.7
56	13.6	14.4	15.2	16.0	16.9	17.7	18.5	19.3	20.1	21.0	21.8	22.6	23.4	24.2	25.1	25.9	26.7	27.5	28.3	29.2	30.0	30.8	31.6	32.4	33.3
58	13.2	14.0	14.8	15.6	16.4	17.3	18.1	18.9	19.7	20.5	21.4	22.2	23.0	23.8	24.6	25.5	26.3	27.1	27.9	28.7	29.6	30.4	31.2	32.0	32.8
60	12.7	13.6	14.4	15.2	16.0	16.8	17.7	18.5	19.3	20.1	20.9	21.8	22.6	23.4	24.2	25.0	25.9	26.7	27.5	28.3	29.1	30.0	30.8	31.6	32.4
62	12.3	13.1	14.0	14.8	15.6	16.4	17.2	18.1	18.9	19.7	20.5	21.3	22.2	23.0	23.8	24.6	25.4	26.3	27.1	27.9	28.7	29.5	30.4	31.2	32.0
64	11.9	12.7	13.5	14.4	15.2	16.0	16.8	17.6	18.5	19.3	20.1	20.9	21.7	22.6	23.4	24.2	25.0	25.9	26.7	27.5	28.3	29.1	29.9	30.8	31.6
66	11.5	12.3	13.1	13.9	14.8	15.6	16.4	17.2	18.0	18.9	19.7	20.5	21.3	22.2	23.0	23.8	24.6	25.4	26.2	27.1	27.9	28.7	29.5	30.4	31.2
68	11.1	11.9	12.7	13.5	14.4	15.2	16.0	16.8	17.6	18.4	19.3	20.1	20.9	21.7	22.5	23.4	24.2	30.0	25.8	26.7	27.5	28.3	29.1	29.9	30.7
70	10.6	11.5	12.3	13.1	13.9	14.7	15.6	16.4	17.2	18.0	18.8	19.7	20.5	21.3	22.1	22.9	23.8	24.6	25.4	26.2	27.0	27.9	28.7	29.5	30.3
72	10.2	11.0	11.9	12.7	13.5	14.3	15.1	16.0	16.8	17.6	18.4	19.2	20.1	20.9	21.7	22.5	23.3	24.2	25.0	25.8	26.6	27.4	28.3	29.1	29.9
74	9.8	10.6	11.4	12.3	13.1	13.9	14.7	15.5	16.4	17.2	18.0	18.8	19.6	20.5	21.3	22.1	22.9	23.7	24.6	25.4	26.2	27.0	27.8	28.7	29.5

Dco values are given in mL/min/mm Hg. The values listed here reflect the Dco as listed in Table 5–6a minus 8.2 (95% confidence interval). Adapted from Crapo and Morris.

Table 5-7a Predicted Normal Diffusing Capacity for Carbon Monoxide (Dco) for Women (STPD)*

Age	Height (cm) 146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	26.0	26.5	27.0	27.6	28.1	28.6	29.2	29.7	30.2	30.8	31.3	31.9	32.4	32.9	33.5	34.0	34.5	35.1	35.6	36.1	36.7	37.2	37.7	38.3	38.8
20	25.7	26.2	26.7	27.3	27.8	28.4	28.9	29.4	30.0	30.5	31.0	31.6	32.1	32.6	33.2	33.7	34.2	34.8	35.3	35.8	36.4	36.9	37.4	38.0	38.5
22	25.4	25.9	26.5	27.0	27.5	28.1	28.6	29.1	29.7	30.2	30.7	31.3	31.8	32.3	32.9	33.4	33.9	34.5	35.0	35.5	36.1	36.6	37.1	37.7	38.2
24	25.1	25.6	26.2	26.7	27.2	27.8	28.3	28.8	29.4	29.9	30.4	31.0	31.5	32.0	32.6	33.1	33.6	34.2	34.7	35.2	35.8	36.3	36.8	37.4	37.9
26	24.8	25.3	25.9	26.4	26.9	27.5	28.0	28.5	29.1	29.6	30.1	30.7	31.2	31.7	32.3	32.8	33.3	33.9	34.4	34.9	35.5	36.0	36.5	37.1	37.6
28	24.5	25.0	25.6	26.1	26.6	27.2	27.7	28.2	28.8	29.3	29.8	30.4	30.9	31.4	32.0	32.5	33.0	33.6	34.1	34.6	35.2	35.7	36.2	36.8	37.3
30	24.2	24.7	25.3	25.8	26.3	26.9	27.4	27.9	28.5	29.0	29.5	30.1	30.6	31.1	31.7	32.2	32.7	33.3	33.8	34.3	34.9	35.4	35.9	36.5	37.0
32	23.9	24.4	25.0	25.5	26.0	26.6	27.1	27.6	28.2	28.7	29.2	29.8	30.3	30.8	31.4	31.9	32.4	33.0	33.5	34.1	34.6	35.1	35.7	36.2	36.7
34	23.6	24.1	24.7	25.2	25.7	26.3	26.8	27.3	27.9	28.4	28.9	29.5	30.0	30.6	31.1	31.6	33.2	32.7	33.2	33.8	34.3	34.8	35.4	35.9	36.4
36	23.3	23.8	24.4	24.9	25.4	26.0	26.5	27.1	27.6	28.1	28.7	29.2	29.7	30.3	30.8	31.3	31.9	32.4	32.9	33.5	34.0	34.5	35.1	35.6	36.1
38	23.0	23.6	24.1	24.6	25.2	25.7	26.2	26.8	27.3	27.8	28.4	28.9	29.4	30.0	30.5	31.0	31.6	32.1	32.6	33.2	33.7	34.2	34.8	35.3	35.8
40	22.7	23.3	23.8	24.3	24.9	25.4	25.9	26.5	27.0	27.5	28.1	28.6	29.1	29.7	30.2	30.7	31.3	31.8	32.3	32.9	33.4	33.9	34.5	35.0	35.5
42	22.4	23.0	23.5	24.0	24.6	25.1	25.6	26.2	26.7	27.2	27.8	28.3	28.8	29.4	29.9	30.4	31.0	31.5	32.0	32.6	33.1	33.6	34.2	34.7	35.2
44	22.1	[illegible]	23.2	23.7	24.3	24.3	25.3	25.9	26.4	26.9	27.5	28.0	28.5	29.1	29.6	30.1	30.7	31.2	31.7	32.3	32.8	33.3	33.9	34.4	[illegible]
46	21.8	22.4	22.9	23.4	24.0	24.5	25.0	25.6	26.1	26.6	27.2	27.7	28.2	28.8	29.3	29.8	30.4	30.9	31.4	32.0	32.5	33.0	33.6	34.1	[illegible]
48	21.5	22.1	22.6	23.1	23.7	24.2	24.7	25.3	25.8	26.3	26.9	27.4	27.9	28.5	29.0	29.5	30.1	30.6	31.1	31.7	32.2	32.8	33.3	33.8	[illegible]
50	21.2	21.8	22.3	22.8	23.4	23.9	24.4	25.0	25.5	26.0	26.6	27.1	27.6	28.2	28.7	29.3	29.8	30.3	30.9	31.4	31.9	32.5	33.0	33.5	[illegible]
52	20.9	21.5	22.0	22.5	23.1	23.5	24.1	24.7	25.2	25.8	26.3	26.8	27.4	27.9	28.4	29.0	29.5	30.0	30.6	31.1	31.6	32.2	32.7	33.2	33.8
54	20.6	21.2	21.7	22.3	22.8	23.3	23.9	24.4	24.9	25.5	26.0	26.5	27.1	27.6	28.1	28.7	29.2	29.7	30.3	30.8	31.3	31.9	32.4	32.9	33.5
56	20.4	20.9	21.4	22.0	22.5	23.0	23.6	24.1	24.6	25.2	25.7	26.2	26.8	27.3	27.8	28.4	28.9	29.4	30.0	30.5	31.0	31.6	32.1	32.6	33.2
58	20.1	20.6	21.1	21.7	22.2	22.7	23.3	23.8	24.3	24.9	25.4	25.9	26.5	27.0	27.5	28.1	28.6	29.1	29.7	30.2	30.7	31.3	31.8	32.3	32.9
60	19.8	20.3	20.8	21.4	21.9	22.4	23.0	23.5	24.0	24.6	25.1	25.6	26.2	26.7	27.2	27.8	28.3	28.8	29.4	29.9	30.4	31.0	31.5	32.0	32.6
62	19.5	20.0	20.5	21.1	21.6	22.1	22.7	23.2	23.7	24.3	24.8	25.3	25.9	26.4	26.9	27.5	28.0	28.5	29.1	29.6	30.1	30.7	31.2	31.7	32.3
64	19.2	19.7	20.2	20.8	21.3	21.8	22.4	22.9	23.4	24.0	24.5	25.0	25.6	26.1	26.6	27.2	27.7	28.2	28.8	29.3	29.8	30.4	30.9	31.5	32.0
66	18.9	19.4	19.9	20.5	21.0	21.5	22.1	22.6	23.1	23.7	24.2	24.1	25.3	25.8	26.3	26.9	27.4	28.0	28.5	29.0	29.6	30.1	30.6	31.2	31.7
68	18.6	19.1	19.6	20.2	20.7	21.2	21.8	22.3	22.8	23.4	23.9	24.5	25.0	25.5	26.1	26.6	27.1	27.7	28.2	28.7	29.3	29.8	30.3	30.9	31.4
70	18.3	18.8	19.3	19.9	20.4	21.0	21.5	22.0	22.6	23.1	23.5	24.2	24.7	25.2	25.8	26.3	26.8	27.4	27.9	28.4	29.0	29.5	30.0	30.6	31.1
72	18.0	18.5	19.1	19.6	20.1	20.7	21.2	21.1	22.3	22.8	23.3	23.9	24.4	24.9	25.5	26.0	26.5	27.1	27.6	28.1	28.7	29.2	29.7	30.3	30.8
74	17.7	18.2	18.8	19.3	19.8	20.4	20.9	21.4	22.0	22.5	23.0	23.6	24.1	24.6	25.2	25.7	26.2	26.8	27.3	27.8	28.4	28.9	29.4	30.0	30.5

*Dco is mL/min/mm Hg = 0.267 H – 0.148 A – 10.34. R^2 = 0.60; SEE = 3.40; 95% confidence interval = 5.74. Definitions of abbreviations: R^2 = coefficient of determination; SEE = standard error of estimate; H = height in cm; A = age in years. STPD = temperature 0°C, pressure 760 mm Hg, and dry (0 water vapor). The regression analysis has been normalized to a standard hemoglobin of 125 g/L (the original equation was normalized to a standard hemoglobin of 146 g/L) by means of Cotes' modification of the relationship described in Roughton and Forster. Adapted from Crapo and Morris.

Table 5-7b Predicted Lower Limit of Normal Diffusing Capacity for Carbon Monoxide (Dco) for Women*

Age	Height (cm) 146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190	192	194
18	20.26	20.76	21.26	21.86	22.36	22.86	23.46	23.96	24.46	25.06	25.56	26.16	26.66	27.16	27.76	28.26	28.76	29.36	29.86	30.36	30.96	31.46	31.96	32.56	33.06
20	19.96	20.46	20.96	21.56	22.06	22.66	23.16	23.66	24.26	24.76	25.26	25.86	26.36	26.86	27.46	27.96	28.46	29.06	29.56	30.06	30.66	31.16	31.66	32.26	32.76
22	19.66	20.16	20.76	21.26	21.76	22.36	22.86	23.36	23.96	24.46	24.96	25.56	26.06	26.56	27.16	27.66	28.16	28.76	29.26	29.76	30.36	30.86	31.36	31.96	32.46
24	19.36	19.86	20.46	20.96	21.46	22.06	22.56	23.06	23.66	24.16	24.66	25.26	25.76	26.26	26.86	27.36	27.86	28.46	28.96	29.46	30.06	30.56	31.06	31.66	32.16
26	19.06	19.56	20.16	20.66	21.16	21.76	22.26	22.76	23.36	23.86	24.36	24.96	25.46	25.96	26.56	27.06	27.56	28.16	28.66	29.16	29.76	30.26	30.76	31.36	31.86
28	18.76	19.26	19.86	20.36	20.86	21.46	21.96	22.46	23.06	23.56	24.06	24.66	25.16	25.66	26.26	26.76	27.26	27.86	28.36	28.86	29.46	29.96	30.46	31.06	31.56
30	18.46	18.96	19.56	20.06	20.56	21.16	21.66	22.16	22.76	23.26	23.76	24.36	24.86	25.36	25.96	26.46	26.96	27.56	28.06	28.56	29.16	29.66	30.16	30.76	31.26
32	18.16	18.66	19.26	19.76	20.26	20.86	21.36	21.86	22.46	22.96	23.46	24.06	24.56	25.06	25.66	26.16	26.66	27.26	27.76	28.36	28.86	29.36	29.96	30.46	30.96
34	17.86	18.36	18.96	19.46	19.96	20.56	21.06	21.56	22.16	22.66	23.16	23.76	24.26	24.86	25.36	25.86	27.46	26.96	27.46	28.06	28.56	29.06	29.66	30.16	30.66
36	17.56	18.06	18.66	19.16	19.66	20.26	20.76	21.36	21.86	22.36	22.96	23.46	23.96	24.56	25.06	25.56	26.16	26.66	27.16	27.76	28.26	28.76	29.36	29.86	30.36
38	17.26	17.86	18.36	18.86	19.46	19.96	20.46	21.06	21.56	22.06	22.66	23.16	23.66	24.26	24.76	25.26	25.86	26.36	26.86	27.46	27.96	28.46	29.06	29.56	30.06
40	16.96	17.56	18.06	18.56	19.16	19.66	20.16	20.76	21.26	21.76	22.36	22.86	23.36	23.96	24.46	24.96	25.56	26.06	26.56	27.16	27.66	28.16	28.76	29.26	29.76
42	16.66	17.26	17.76	18.26	18.86	19.36	19.86	20.46	20.96	21.46	22.06	22.56	23.06	23.66	24.16	24.66	25.26	25.76	26.26	26.86	27.36	27.86	28.46	28.96	29.46
44	16.36	16.96	17.46	17.96	18.56	18.56	19.56	20.16	20.66	21.16	21.76	22.26	22.76	23.36	23.86	24.36	24.96	25.46	25.96	26.56	27.06	27.56	28.16	28.66	29.16
46	16.06	16.66	17.16	17.66	18.26	18.76	19.26	19.86	20.36	20.86	21.46	21.96	22.46	23.06	23.56	24.06	24.66	25.16	25.66	26.26	26.76	27.26	27.86	28.36	28.86
48	15.76	16.36	16.86	17.36	17.96	18.46	18.96	19.56	20.06	20.56	21.16	21.66	22.16	22.76	23.26	23.76	24.36	24.86	25.36	25.96	26.46	27.06	27.56	28.06	28.66
50	15.46	16.06	16.56	17.06	17.66	18.16	18.66	19.26	19.76	20.26	20.86	21.36	21.86	22.46	22.96	23.56	24.06	24.56	25.16	25.66	26.16	26.76	27.26	27.76	28.36
52	15.16	15.76	16.26	16.76	17.36	17.76	18.36	18.96	19.46	20.06	20.56	21.06	21.66	22.16	22.66	23.26	23.76	24.26	24.86	25.36	25.86	26.46	26.96	27.46	28.06
54	14.86	15.46	15.96	16.56	17.06	17.56	18.16	18.66	19.16	19.76	20.26	20.76	21.36	21.86	22.36	22.96	23.46	23.96	24.56	25.06	25.56	26.16	26.66	27.16	27.76
56	14.66	15.16	15.66	16.26	16.76	17.26	17.86	18.36	18.86	19.46	19.96	20.46	21.06	21.56	22.06	22.66	23.16	23.66	24.26	24.76	25.26	25.86	26.36	26.86	27.46
58	14.36	14.86	15.36	15.96	16.46	16.96	17.56	18.06	18.56	19.16	19.66	20.16	20.76	21.26	21.76	22.36	22.86	23.36	23.96	24.46	24.96	25.56	26.06	26.56	27.16
60	14.06	14.56	15.06	15.66	16.16	16.66	17.26	17.76	18.26	18.86	19.36	19.86	20.46	20.96	21.46	22.06	22.56	23.06	23.66	24.16	24.66	25.26	25.76	26.26	26.86
62	13.76	14.26	14.76	15.36	15.86	16.36	16.96	17.46	17.96	18.56	19.06	19.56	20.16	20.66	21.16	21.76	22.26	22.76	23.36	23.86	24.36	24.96	25.46	25.96	26.56
64	13.46	13.96	14.46	15.06	15.56	16.06	16.66	17.16	17.66	18.26	18.76	19.26	19.86	20.36	20.86	21.46	21.96	22.46	23.06	23.56	24.06	24.66	25.16	25.76	26.26
66	13.16	13.66	14.16	14.76	15.26	15.76	16.36	16.86	17.36	17.96	18.46	18.36	19.56	20.06	20.56	21.16	21.66	22.26	22.76	23.26	23.86	24.36	24.86	25.46	25.96
68	12.86	13.36	13.86	14.46	14.96	15.46	16.06	16.56	17.06	17.66	18.16	18.76	19.26	19.76	20.36	20.86	21.36	21.96	22.46	22.96	23.56	24.06	24.56	25.16	25.66
70	12.56	13.06	13.56	14.16	14.66	15.26	15.76	16.26	16.86	17.36	17.76	18.46	18.96	19.46	20.06	20.56	21.06	21.66	22.16	22.66	23.26	23.76	24.26	24.86	25.36
72	12.26	12.76	13.36	13.86	14.36	14.96	15.46	15.36	16.56	17.06	17.56	18.16	18.66	19.16	19.76	20.26	20.76	21.36	21.86	22.36	22.96	23.46	23.96	24.56	25.06
74	11.96	12.46	13.06	13.56	14.06	14.66	15.16	15.66	16.26	16.76	17.26	17.86	18.36	18.86	19.46	19.96	20.46	21.06	21.56	22.06	22.66	23.16	23.66	24.26	24.76

*Dco values are given in mL/min/mm Hg. The values listed here reflect the Dco as listed in Table 5–7a minus 5.74 (95% confidence interval). Adapted from Crapo and Morris.

5.4f Cardiopulmonary Exercise Testing

Cardiopulmonary exercise testing is sometimes useful in assessing whether an individual's complaint of dyspnea (see Table 5-1) is a result of respiratory or other conditions. A person's cardiac and conditioning status must be considered in performing the test and in interpreting the results.

The cardiopulmonary exercise gas-exchange measurement can be an additional means of assessing the severity and cause of exercise intolerance. Simultaneous measurement of carbon dioxide (CO_2) production, minute ventilation, and heart rate allows determination of whether exercise capacity limitation is due to cardiac, pulmonary, or coexisting impairments. When properly performed and interpreted, these tests can help differentiate pulmonary impairment from cardiac impairment or physical deconditioning effects.[24]

Exercise capacity is measured by oxygen consumption per unit time ($\dot{V}o_2$) in milliliters per kilogram multiplied by minutes (mL/[kg•min]) or in metabolic equivalents (METS), a unit of expended energy equal to 3.5 mL/(kg•min) oxygen consumption. MET is discussed in Chapter 3 in the sections on the heart and aorta. Generally, an individual can sustain a work level equal to 40% of his or her measured maximum $\dot{V}o_2$ for an 8-hour period.[25] Table 5-8 shows the relationship between work intensity and oxygen consumption.

Table 5-8 Impairment Classification for Prolonged Physical Work Intensity by Oxygen Consumption*

Work Intensity for 70-kg Person*	Oxygen Consumption	Excess Energy Expenditure
Light work	7 mL/kg; 0.5 L/min	< 2 METS
Moderate work	8-15 mL/kg; 0.6-1.0 L/min	2-4 METS
Heavy work	16-20 mL/kg; 1.1-1.5 L/min	5-6 METS
Very heavy work	21-30 mL/kg; 1.6-2.0 L/min	7-8 METS
Arduous work	> 30 mL/kg; > 2.0 L/min	> 8 METS

*Adapted from Astrand and Rodahl. mL/kg indicates milliliter per kilogram; L/min, liter per minute; and METS, metabolic equivalents (multiples of resting oxygen uptake).

Use cardiopulmonary exercise testing judiciously since these studies can be difficult to perform, are more expensive, and are sometimes more invasive than conventional tests. Ordinarily, exercise capacity measurements are not used to study individuals with normal results on routine pulmonary function tests. However, they can be helpful when the results of pulmonary function tests do not correlate with the individual's symptoms or when additional information is needed to clarify the nature and severity of an impairment.[27] Do not use exercise capacity measurements to study individuals with medical contraindications such as unstable cardiac disease.

Arterial Blood Gas Analysis

Because of its invasive nature, use arterial blood gas analysis only when necessary to evaluate pulmonary impairment. Arterial blood gas analysis results may be outside the normal range for reasons other than pulmonary disease. For most individuals with obstructive lung disease, exercise capacity correlates better with FEV_1 than arterial partial pressure of oxygen (Po_2). For purposes of evaluating permanent impairment, hypoxia must be measured on two separate occasions at least 4 weeks apart.

Pulse oximetry, which is less invasive than arterial blood gas, often provides an adequate estimate of hypoxia. Arterial blood gases, although more invasive, provide a more accurate measurement of hypoxia. Physicians should use their clinical judgment as to which measurement is needed, based on individual assessment.

An arterial blood gas determination may indicate the presence of severe impairment even when a person's condition is stable and he or she is receiving optimal therapy. An arterial Po_2 of less than 55 mm Hg is evidence of severe impairment when an individual is examined at rest while breathing room air at sea level. Severe impairment may also be diagnosed with an arterial Po_2 of less than 60 mm Hg if the person also has one or more of the following conditions: pulmonary hypertension, cor pulmonale, increasingly severe hypoxia during exercise testing, or erythrocytosis.

5.4g Criteria for Rating Impairment Due to Respiratory Disease

Table 5-12 presents criteria for estimating the permanent impairment rating for different respiratory conditions, discussed below. Perform spirometry and Dco on each person being evaluated.[3] $\dot{V}o_2$max may provide additional information in selected individuals when indicated. The person must meet all of the listed criteria except for $\dot{V}o_2$max in order to be considered nonimpaired. At least one of the listed criteria must be fulfilled to place an individual in any class with an impairment rating. As discussed in Chapter 1, in individuals where the preinjury or preillness values differ from the population-listed values, the examiner

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may depart from the population-listed normal values for determining an impairment rating, using the preinjury and preillness "normal" value, and explain the reason for the departure.

5.5 Asthma

Asthma is an airway inflammatory disease characterized by episodic and variable airflow limitation and airway hyperresponsiveness. A diagnosis of asthma requires relevant symptoms (eg, cough, sputum, wheeze, chest tightness, or breathlessness) and *either* evidence of airflow obstruction that is partially or completely reversible (either spontaneously or after treatment) or airway reactivity to methacholine *or* histamine in the absence of airflow limitation.[10]

Variable airflow obstruction can be detected with pulmonary function testing, which shows a reversible obstructive airway pattern. Airway hyperresponsiveness is detected by bronchial challenge testing with methacholine or histamine.[28] Airway hyperresponsiveness is defined as a positive methacholine or histamine challenge, as reflected by a decrease in FEV_1 of 20% (PC_{20}) from baseline, upon provocation with less than or equal to 8 mg/mL of methacholine or histamine using the tidal breathing method or its equivalent.[1,13] The results from methacholine testing should be expressed as the provocation concentration to cause a fall in FEV_1 of 20% (PC_{20}).

While different varieties of asthma exist, they all share an underlying commonality of airway hyperresponsiveness. Occupational asthma represents a special subset of asthma subjects. This abnormality has now surpassed pneumoconiosis as the most commonly reported occupational lung disease linked to a particular occupational environment or agent. Besides directly causing occupational asthma, work exposures can acutely exacerbate an underlying asthmatic condition, which can subsequently return to preexposure baseline status with removal from exposure. Work exposures can also cause a more permanent change in an underlying asthmatic condition, which can persist even after removal from exposure. If an individual's asthma is worsening at work, it is important to remove the individual from exposure or, at a minimum, reduce exposure and reevaluate his or her condition when it has stabilized. Although prevention is optimal, medication can substantially modify symptoms and the clinical course of asthma.

Occupational asthma can be caused by sensitizers or irritants. Sensitizers are classified as either high molecular weight or low molecular weight. High-molecular-weight sensitizers of animal or plant origin include animal dander or grain dust. Low-molecular-weight sensitizers, typically organic or inorganic chemicals, include diisocyanates. Sensitizers generally require a latency period for the development of immunologic responsiveness. This latency period may last from a few weeks to several years after first exposure.

In the case of sensitizer-induced asthma (such as toluene diisocyanate or latex), there is a potential for severe exacerbation or fatality upon reexposure. Although many individuals with occupational asthma improve after removal from exposure to either low-molecular-weight or high-molecular-weight sensitizers, more than half fail to recover completely, even after 2 or more years since the last exposure. Those who are sensitized to occupational agents ideally should discontinue further exposure. Both the individual and his or her physician need to monitor the course of asthmatic symptoms, especially if ongoing exposure occurs. Many can be identified as having a particular type of asthma. For those who have allergic asthma, exercise-induced and irritant-induced components may be identified as well.

Irritant-induced asthma, known as reactive airways dysfunction syndrome (RADS), may result from a single high-level exposure to a highly irritating gas, fume, mist, or vapor. The diagnosis of RADS requires (1) inhalation exposure to an acutely irritating concentration of a substance, (2) onset of symptoms (cough, wheezing cough, or dyspnea) within 24 hours after exposure with persistent respiratory symptoms, and (3) functional abnormalities (airway hyperresponsiveness) for more than 3 months, with no preexisting respiratory disease.[30]

Irritant-induced asthma often improves with time: some people may resume their former employment. However, some individuals experience persistent respiratory impairment. Individual assessment is important because reducing the degree and duration of exposure may control symptoms in some people, but complete removal from exposure may be necessary to control symptoms in others.

Occupational and nonoccupational asthma impairment evaluations follow the same guidelines. Both require a thorough review of current occupational and home environments and the likelihood of similar exposures in subsequent workplaces. When assessing impairment due to asthma, information is needed from both clinical and physiologic parameters. The AMA recommends that the examiner follow ATS guidelines when assessing asthma impairment and include measurements of pulmonary mechanics, airway hyperresponsiveness, and medication requirements.[1] Table 5-9 lists the criteria for impairment evaluation for asthma severity. The examiner evaluates the indices listed, including the minimum medication needed to control the individual's asthma.

Before performing an impairment rating for asthma, the examiner needs to determine that the pattern of asthma is clinically stable and well treated, based upon fulfilling the objectives of treatment as detailed by the expert panel report of the National Asthma Education Program.[8,9] The objectives of treatment are: (1) to achieve control or the best overall results (least symptoms, least need for ß-adrenergic agonists when taken only if required, best expiratory flow rates, least diurnal variation of flow rates, and least side effects from medication); (2) to use the minimum amount of medication to maintain control or the best overall results; and (3) to treat exacerbations early to prevent them from becoming severe.

In 1993, the ATS developed guidelines for the evaluation of impairment and/or disability in individuals with asthma.[1] According to the ATS statement, asthma necessitated special guidelines because of its distinct features, including: (1) variable airflow obstruction and change in clinical status over time; (2) partial or complete reversibility of airflow obstruction with therapy; (3) nonspecific airway hyperresponsiveness to irritants such as dusts, gases, fumes, or smoke; and (4) sensitization to occupational agents producing airway inflammation that with repeated exposure may become chronic and irreversible.

In assessing an individual with suspected asthma, if the prebronchodilator FEV_1 is above the lower limit of normal, use methacholine challenge to assess airway responsiveness. The degree of airway hyperresponsiveness and scoring are illustrated in Table 5-9. If the prebronchodilator FEV_1 is below the lower limit of normal, the degree of reversibility is assessed with inhaled bronchodilators (see Table 5-9 for scoring).

To perform the evaluation at a state of maximal medical improvement, choose the optimal drug treatment to minimize symptoms. The type and extent of necessary medication is one measure of impairment severity (see Table 5-9 for scoring). Use of medication, as a score for impairment, is only used in individuals who have a diagnosis of asthma.

The scores for postbronchodilator FEV_1, reversibility of FEV_1 (or PC_{20}), and medication use are added to obtain a summary score for respiratory impairment (see Table 5-10). ATS criteria do not assign impairment percentages. If an impairment percentage is needed, refer to Table 5-10, which assigns impairment classes and percentages to an asthma score. The authors of this chapter have assigned these impairment percentages according to the ATS criteria, based on their clinical judgment. In determining the percent impairment for a particular class, the examiner needs to consider how the person's asthma affects the ability to perform activities of daily living.

Table 5-9 Impairment Classification for Asthma Severity*

Score	Postbronchodilator FEV_1	% of FEV_1 Change (Reversibility) or	PC_{20} mg/mL or Equivalent (Degree of Airway Hyperresponsiveness)†	Minimum Medication‡
0	≥ lower limit of normal	<10%	> 8 mg/mL	No medication
1	≥ 70% of predicted	10%-19%	8 mg/mL to > 0.6 mg/mL	Occasional but not daily bronchodilator and/or occasional but not daily cromolyn
2	60%-69% of predicted	20%-29%	0.6 mg/mL to > 0.125mg/mL	Daily bronchodilator and/or daily cromolyn and/or daily low-dose inhaled corticosteroid (≤ 800 µg of beclomethasone or equivalent)
3	50%-59% of predicted	≥ 30%	≤ 0.125 mg/mL	Bronchodilator on demand and daily high-dose inhaled corticosteroid (>800 µg of beclomethasone or equivalent) or occasional course (one to three courses a year) of systemic corticosteroid
4	<50% of predicted			Bronchodilator on demand and daily high-dose inhaled corticosteroid (>1000 µg of beclomethasone or equivalent) and daily or every other day systemic corticosteroid

*FEV_1 indicates forced expiratory volume in the first second; PC_{20} is the provocative concentration that causes a 20% fall in FEV_1. Add the scores for postbronchodilator FEV_1, reversibility of FEV_1 (or PC_{20}), and medication use to obtain a summary severity score for rating respiratory impairment.

†When FEV_1 is greater than the lower limit of normal, PC_{20} should be determined and used for rating of impairment; when FEV_1 is less than 70% of the predicted, the degree of reversibility should be used; and when FEV_1 is between 70% of the predicted and the lower limit of normal, either reversibility or PC_{20} can be used. The score for minimum medication use is added to the appropriate measurement criteria outlined above.

‡Need for minimum medication should be demonstrated by the treating physician, for example, through previous records of exacerbation when medications have been reduced. Adapted from ATS guidelines.[1]

Table 5-10 Impairment Rating for Asthma*

Total Asthma Score	% Impairment Class	Impairment of the Whole Person
0	1	0%
1-5	2	10%-25%
6-9	3	26%-50%
10-11 or asthma not controlled despite maximal treatment, ie, FEV_1 remaining <50% despite use of > 20 mg/day of prednisone	4	51%-100%

*The impairment rating is calculated as the sum of the individual's scores from Table 5-9. FEV_1 indicates forced expiratory volume in the first second.

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5.6 Obstructive Sleep Apnea

Individuals with obstructive sleep apnea experience intermittent, repetitive occlusions of the upper airway during sleep, when the pharyngeal muscles are relaxed. These occlusion periods produce airflow cessation at the nose and mouth that leads to progressive hypoxia, which then causes arousal from sleep. The affected person awakens briefly and reestablishes airway patency, resuming airflow with a loud snore or snorting sound. Because of recurrent awakenings during the night, there is disrupted sleep architecture, without restful sleep. Symptoms of sleep apnea include a history of loud snoring, unsatisfactory sleep pattern, daytime somnolence, cognitive dysfunction, and hypertension. Between 60% and 90% are obese and may have a large neck circumference. When the disorder is severe, erythrocytosis, pulmonary hypertension, and cor pulmonale may result.

Even if total occlusion of the upper airway does not occur during sleep, partial obstruction can lead to significant reduction in airflow and produce obstructive hypopnea, which causes oxyhemoglobin saturation reduction and similar clinical and physiologic abnormalities as seen in obstructive sleep apnea.

A variant of obstructive sleep apnea is the obesity hypoventilation syndrome. The weight of the chest wall in morbidly obese individuals may limit respiratory movements during sleep and wakefulness. As a result, both hypoxia and hypercapnia persist throughout the day as well as during sleep. The same physiologic consequences occur in these individuals as in those with obstructive sleep apnea. In fact, obstructive sleep apnea and obesity hypoventilation syndrome may coexist in the same person.

People affected by obstructive sleep apnea are at significantly increased risk of being involved in motor vehicle collisions. Severe daytime somnolence may prevent them from functioning adequately. Subtle changes in neuropsychological function include memory abnormalities and worsened motor coordination and mood that may affect the person's daily life.

A diagnosis of obstructive sleep apnea is confirmed by nocturnal polysomnography in an accredited sleep laboratory. Once the diagnosis has been established, prescribe continuous positive airway pressure (CPAP) through a nasal device for use during sleep to maintain upper airway patency. Weight loss is the most effective means of long-term management and a possible cure for obstructive sleep apnea if a lower body mass index can be maintained.[32]

Grading obstructive sleep apnea severity depends on the number of apnea/hypopnea episodes observed in polysomnography and the severity of hypoxia caused by these episodes. There are no standard, well-documented criteria for determining the level of impairment based on the results of polysomnography. For purposes of impairment rating as discussed in this chapter, refer to the judgment of a sleep specialist.

5.7 Hypersensitivity Pneumonitis

Hypersensitivity pneumonitis, also known as extrinsic allergic alveolitis, is a granulomatous interstitial and bronchiolar lung disease caused by immune sensitization to organic dusts and some low-molecular-weight chemical antigens. A wide variety of antigenic substances are known to cause this disease. The acute disease is characterized by the onset of respiratory and constitutional symptoms beginning 4 to 8 hours after exposure to the offending material. Symptoms include chest tightness, cough, dyspnea, fever, chills, malaise, and myalgias. Pulmonary function tests in the acute phase of the disease show volume restriction and decreased diffusing capacity. Hypoxia may be demonstrated by pulse oximetry or arterial blood gas testing. Chest radiographs may be normal but often show diffuse micronodular changes in the pulmonary parenchyma. When the person is removed from exposure, the symptoms, physiologic changes, and chest radiographic abnormalities begin to resolve within 1 to 2 days, although they may take 4 to 6 weeks for complete resolution.

In the subacute and chronic presentations of hypersensitivity pneumonitis, the predominant symptoms include exertional dyspnea and cough; some report sputum production, anorexia, fatigue, and weight loss. Pulmonary function studies often show mixed restriction and obstruction with isolated obstructive changes in some individuals. With repeated exposures, pulmonary fibrotic changes may occur as the abnormalities become chronic and irreversible.[33]

Permanently restrict individuals with hypersensitivity pneumonitis from exposure to the sensitizing agent. If pulmonary fibrosis has not supervened, normal pulmonary function may be reestablished. However, the onset of pulmonary fibrosis is likely to produce respiratory impairment and may limit other types of employment. Once the acute episode has resolved and the condition is stable, the examiner may rate the degree of permanent impairment according to the criteria given in Table 5-12.

Asthma, pneumoconiosis, and hypersensitivity pneumonitis may require that the person refrain from working in a specific occupational setting where he or she is exposed to the offending agent. If reassigned where no ongoing exposure occurs, the individual may not have a permanent respiratory impairment.

5.8 Pneumoconiosis

Pneumoconiosis is a term used to describe diseases resulting from the inhalation of mineral dusts such as silica, coal, and asbestos, and metals such as cobalt and beryllium. The radiologic and pathologic patterns of pneumoconiosis from these dusts are usually quite distinct and beyond the scope of this chapter. Latency between exposure to these dusts and development of disease varies, but disease can occur anywhere from 10 up to 30 years after initial exposure.[14]

The severity of impairment related to pneumoconiosis depends on the characteristics of the specific dust inhaled, the dust burden retained in the lungs, the susceptibility of the individual, and the length of time since first exposure. Under some circumstances, the parenchymal changes on chest radiograph may be progressive even after removal from exposure and may or may not be associated with physiologic impairment. Persons who develop pneumoconiosis should limit further exposure to the offending agent, particularly if radiographic changes have occurred at a relatively young age or if there is associated physiologic impairment. However, these individuals may be capable of working at other jobs where the offending dust is not present. See Table 5-12 for criteria for assessment of impairment due to pneumoconiosis.

5.9 Lung Cancer

All persons with lung cancer are severely impaired at diagnosis. At reevaluation 1 year after the diagnosis is established, if the person is found to be free of all evidence of tumor recurrence, then he or she is evaluated according to criteria listed in Table 5-12. If there is still evidence of tumor, the he or she is considered to be severely impaired (class 4 impairment); if the tumor recurs, the person will also be considered to be severely impaired (class 4 impairment). Table 5-11 (the Karnofsky scale), specifically developed to describe the capabilities of individuals with cancer, may be used to further describe the capabilities of a person with lung cancer and enable categorization within a particular class.

Table 5-11 Scale for Judging Capabilities of Subjects With Cancer*

Grade	Description
0	Fully active; able to carry on all predisease activities without restrictions
1	Restricted in physically strenuous activity but ambulatory and able to carry out light tasks, such as light work in home or office
2	Requires occasional to considerable care for most needs and frequent medical care
3	Capable only of limited self-care and confined to bed or chair at least half of waking hours
4	Almost totally impaired; cannot care for self, and totally confined to bed or chair

Adapted from Moussa et al.[9]

5.10 Permanent Impairment Due to Respiratory Disorders

Table 5-12 lists criteria for estimating the permanent impairment rating due to respiratory disorders, using pulmonary function and exercise test results. Perform spirometry and Dco on each person being evaluated.[3] $\dot{V}o_2max$ may provide additional information in selected individuals when indicated. Determine the predicted values for FVC, FEV_1, and Dco using Tables 5-2a through 5-7a, and calculate the percent predicted (observed/predicted value). Determine the lower limit of normal for FVC, FEV_1, and Dco using Tables 5-2b through 5-7b. The person must meet all of the listed criteria except for $\dot{V}o_2max$ in order to be considered nonimpaired. At least one of the listed criteria must be fulfilled to place an individual in any class with an impairment rating. As discussed in Chapter 1, in individuals where the preinjury or preillness values differ from the population-listed values, the examiner may depart from the population-listed normal values for determining an impairment rating, using the preinjury and preillness "normal" value, and explain the reason for the departure.

The classification system in Table 5-12 considers only pulmonary function measurements for an impairment rating. It is recognized that pulmonary impairment can occur that does not significantly impact pulmonary function and exercise test results but that does impact the ability to perform activities of daily living, such as with bronchiectasis.

In these limited cases, the physician may assign an impairment rating based on the extent and severity of pulmonary dysfunction and the inability to perform activities of daily living (see Table 1-2). Measured losses of pulmonary function, and corresponding impairment classes, result in a loss in the ability to perform some activities of daily living. The physician can use these associations as a reference. A detailed description with supporting, objective documentation of the type of pulmonary impairment and its impact on the ability to perform activities of daily living is required.

Table 5-12 Impairment Classification for Respiratory Disorders, Using Pulmonary Function and Exercise Test Results*

Pulmonary Function Test	Class 1 0% Impairment of the Whole Person	Class 2 10%-25% Impairment of the Whole Person	Class 3 26%-50% Impairment of the Whole Person	Class 4 51%-100% Impairment of the Whole Person
FVC	Measured FVC ≥ lower limit of normal (see Tables 5-2b and 5-3b) *and*	≥ 60% of predicted and < lower limit of normal *or*	≥ 51% and ≤ 59% of predicted *or*	≤ 50% of predicted *or*
FEV_1	Measured FEV_1 ≥ lower limit of normal (see Tables 5-4b and 5-5b) *and*	≥ 60% of predicted and < lower limit of normal *or*	≥ 41% and ≤ 59% of predicted *or*	≤ 40% of predicted *or*
FEV_1/FVC	FEV_1/FVC ≥ lower limit of normal† *and*			
Dco	Dco ≥ lower limit of normal (see Tables 5-6b and 5-7b) *or*	≥ 60% of predicted and < lower limit of normal *or*	≥ 41% and ≤ 59% of predicted *or*	≤ 40% of predicted *or*
$\dot{V}o_2max$	$\dot{V}o_2max$ ≥ 25 mL/(kg·min) *or* > 7.1 METS	≥ 20 and < 25 mL/(kg·min) *or* 5.7-7.1 METS	≥ 15 and < 20 mL/(kg·min) *or* 4.3 to < 5.7 METS	< 15 mL/(kg·min) *or* < 1.05 L/min *or* < 4.3 METS

*FVC indicates forced vital capacity; FEV_1, forced expiratory volume in the first second; Dco, diffusing capacity for carbon monoxide; $\dot{V}o_2max$, maximum oxygen consumption; and METS, metabolic equivalents (multiples of resting oxygen uptake). Dco is primarily of value for persons with restrictive lung disease. In classes 2 and 3, if FVC, FEV_1, and FEV_1/FVC are normal and Dco is between 41% and 79%, then an exercise test is required to determine level of impairment.

†Refer to Crapo RO, Morris AH, Gardner RM for the lower limit of normal for FEV_1/FVC.[3]

Class 1 0% Respiratory Impairment
Measured FVC: ≥ lower limit of normal (see Tables 5-2b and 5-3b)
and
Measured FEV_1: ≥ lower limit of normal (see Tables 5-4b and 5-5b)
and
FEV_1/FVC: ≥ lower limit of normal
and
Dco: ≥ lower limit of normal (see Tables 5-6b and 5-7b)
or
$\dot{V}o_2$max: ≥ 25 mL/(kg•min) *or* 7.1 METS

Example 5-1
0% Impairment Due to Chronic Bronchitis

Subject: 40-year-old man.

History: Foundry worker for 21 years; nonsmoker.

Current Symptoms: Daily productive cough for several years; on most days for 3 consecutive months; no dyspnea on exertion.

Physical Exam: Height: 188 cm (6 ft 2 in); weight 95.3 kg (210 lb).

Clinical Studies: Scattered rhonchi in both lungs. Chest radiograph: normal. FVC (L): observed 5.67; predicted 5.77; observed/predicted 98%. FEV_1 (L): observed 4.51; predicted 4.62; observed/predicted 98%. FEV_1/FVC: observed 79.5%. Dco: observed/predicted 91%.

Diagnosis: Chronic bronchitis.

Impairment Rating: 0% impairment of the whole person.

Comment: Pulmonary function tests normal. If earlier pulmonary function tests available, comparison with current results recommended.

Example 5-2
0% Impairment Due to Respiratory Disease

Subject: 50-year-old man.

History: Delivery truck driver for 25 years; hospitalized for anteroseptal myocardial infarction 3 months earlier; returned to work. Progressive exercise program. Smoker: 35 pack-year history.

Current Symptoms: Shortness of breath carrying three boxes up a flight of stairs. Allowed to return to work after beginning a progressive exercise program.

Physical Exam: Height: 188 cm (6 ft 2 in); weight 86.4 kg (190 lb). Normal breath sounds and cardiac examination.

Clinical Studies: Chest radiograph: left ventricle enlargement: normal lungs. FVC (L): observed 5.28; predicted 5.56; observed/predicted 95%. FEV_1 (L): observed 3.85; predicted 4.37; observed/predicted 88%. FEV_1/FVC: observed 73%. Dco: 91%. $\dot{V}o_2$: 18 mL/kg.

Diagnosis: Inadequate cardiac output resulting from myocardial infarction.

Impairment Rating: 0% impairment of the whole person based on respiratory function alone.

Comment: Pulmonary function studies indicate class 1 and no respiratory impairment. See *Guides* Chapters 3 and 4 to determine cardiovascular system impairment.

Class 2 10%-25% Respiratory Impairment
Measured FVC: ≥ 60% of predicted and < lower limit of normal
or
Measured FEV_1: ≥ 60% of predicted and < lower limit of normal
or
Dco: ≥ 60% of predicted and < lower limit of normal
or
$\dot{V}o_2$max: ≥ 20 and < 25 mL/(kg•min) *or* 5.7-7.1 METS

Example 5-3
10% to 25% Impairment Due to Respiratory Disease

Subject: 54-year-old man.

History: Retired power plant mechanic; routine asbestos exposure from ages 18 to 37. Currently 10-year nonsmoker; previous 24 pack-year history of smoking.

Current Symptoms: Dyspnea when walking on level ground with others his age.

Physical Exam: Height 175 cm (5 ft 9 in); weight 115 kg (253 lb). Auscultation: shortened expiratory phase; no crackles or wheezes. Diminished posterior breath sounds at both lung bases.

Clinical Studies: On radiograph: moderately extensive focal pleural thickening; diffuse pleural thickening of left lateral chest wall extending into left costophrenic angle. Calcified pleural plaque in left hemidiaphragm. No interstitial changes. FVC (L): observed 3.00; predicted 4.69; observed/predicted 64%. FEV_1 (L): observed 2.43; predicted 3.74; observed/predicted 65%. FEV_1/FVC: observed 81%. Dco: observed/predicted 78%.

Diagnosis: Diffuse asbestos-related pleural changes with restrictive physiology. No evidence of parenchymal asbestosis.

Impairment Rating: 10% to 25% impairment of the whole person.

Comment: Diffuse pleural fibrosis may cause permanent restrictive impairment.

Example 5-4
10% to 25% Impairment Due to Respiratory Disease

Subject: 58-year-old woman.

History: Teacher; several years' daily cough with morning sputum production. Smoked 1.5 packs per day from ages 16 to 58. No asthma, pneumonia, or exposure to hazardous dusts, chemicals, or fumes.

Current Symptoms: Some wheezing, especially with colds. No dyspnea, chest pain, or hemoptysis.

Physical Exam: Height: 168 cm (5 ft 6 in); weight: 61 kg (135 lb). Forced exhalation expiratory wheeze.

Clinical Studies: Chest radiograph: normal. FVC (L): observed 2.73; predicted 3.41; observed/predicted 80%. FEV_1 (L): observed 1.83; predicted 2.69; observed/predicted 68%. FEV_1/FVC: observed 67%. Dco: observed/predicted 73%. $\dot{V}o_2$max: 20 mL/kg/min.

Diagnosis: Chronic bronchitis with mild airflow obstruction.

Impairment Rating: 10% to 25% impairment of the whole person.

Comment: Mild airflow obstruction caused by cigarette smoking.

Example 5-5
10% to 25% Impairment Due to Respiratory Disease

Subject: 48-year-old man.

History: Dairy farmer; various hospitalizations for pneumonia. No cardiovascular disease, asthma, or cigarette smoking. Works with hay stored in barn; particularly dusty during winter.

Current Symptoms: Persistent nonproductive cough; short of breath on exertion.

Physical Exam: Height: 177 cm (5 ft 10 in); weight: 77 kg (170 lb). Persistent bilateral end-inspiratory crackles in posterior and lateral bases.

Clinical Studies: Chest radiograph: diffuse fibrotic process throughout both lung fields. Prior radiographs: no change over 5 years. FVC (L): observed 3.47; predicted 4.99; observed/predicted 70%. FEV_1 (L): observed 2.69; predicted 4.00; observed/predicted 67%. FEV_1/FVC: observed 78%. Dco: observed/predicted 64%. $\dot{V}o_2$max: 20 mL/kg/min.

Diagnosis: Hypersensitivity pneumonitis.

Impairment Rating: 10% to 25% impairment of the whole person.

Comment: Pulmonary function impairment; permanently restrict exposure to moldy hay.

Example 5-6
10% to 25% Impairment Due to Respiratory Disease

Subject: 25-year-old man.

History: Self-employed auto body worker; no previous history of asthma. Had been spray painting for 5 years with paints containing hexamethylene diisocyanate (HDI), one of the asthma-causing diisocyanates. Admitted to the hospital with wheezing; a diagnosis of asthma was made; was started on asthma medications. After 2 years of avoidance of HDI, while compliantly following medication regimen of high-dose inhaled corticosteroids and, as needed, beta-agonist bronchodilator, minimum medication need score was 3.

Current Symptoms: Exercise-related and nocturnal coughing and wheezing.

Physical Exam: Normal.

Clinical Studies: Spirometry without bronchodilators and diffusing capacity: normal, but a methacholine challenge test showed airway hyperreactivity with PC_{20} methacholine of 5 mg/mL (score 1).

Diagnosis: Occupational asthma due to HDI.

Impairment Rating: Asthma score (Table 5-9): 4; 10% to 25% impairment of the whole person (Table 5-10).

Comment: No further exposure to diisocyanates is recommended.

Class 3 26%-50% Respiratory Impairment
Measured FVC: ≥ 51% and ≤ 59% of predicted
or
Measured FEV_1: ≥ 41% and ≤ 59% of predicted
or
Dco: ≥ 41% and ≤ 59% of predicted
or
$\dot{V}o_2max$: ≥ 15 and < 20 mL/(kg·min) or 4.3 to < 5.7 METS

Example 5-7
26% to 50% Impairment Due to Respiratory Disease

Subject: 60-year-old man.

History: Insulator for 40 years; mixed powdered asbestos with water and applied it to pipes and steel beams for first 20 years. Denies cough, wheezing, or chest pain. Nonsmoker. No asthma, pneumonia, or other medical disorders. No medications.

Current Symptoms: Increasing dyspnea for 5 years; difficulty keeping up with others the same age. Unable to walk upstairs past second flight.

Physical Exam: Height: 170 cm (5 ft 7 in); weight: 70.5 kg (155 lb). Questionable finger clubbing; bilateral end-inspiratory crackles at lung bases. Cardiac examination: normal.

Clinical Studies: Chest radiograph: moderately pronounced, small, linear, irregular opacities at lung bases; small, bilateral pleural plaques. FVC (L): observed 2.35; predicted 4.27; observed/predicted 55%. FEV_1 (L): observed 2.10; predicted 3.38; observed/predicted 62%. FEV_1/FVC: observed 89%. Dco: observed 16.0; predicted 30.8; observed/predicted 52%. $\dot{V}o_2max$: 16 mL/kg/min.

Diagnosis: Asbestosis and asbestos-related pleural plaques.

Impairment Rating: 26% to 50% impairment of the whole person.

Comment: Interstitial lung disease with crackles, decreased vital capacity, and decreased gas exchange. Decreased oxygen uptake probably due to pulmonary dysfunction.

Example 5-8
26% to 50% Impairment Due to Asthma

Subject: 33-year-old woman.

History: Natural rubber latex glove inspector for 7 years; no prior history of asthma, but history of eczema. When away from work, symptoms persisted, exacerbated by weather changes, anxiety, or moderate exercise. Symptoms were less severe than when working with latex.

Current Symptoms: Episodic cough, shortness of breath, chest tightness, and occasional wheezing, with symptom onset within 10 minutes of [illegible] work and persistent throughout the day. J[illegible] involved testing surgical latex gloves for [illegible] inflating with compressed air, which relea[illegible] cornstarch glove powder into the air. Sym[illegible] improved, but did not resolve, while on a 12-day vacation.

Physical Exam: Diffuse wheezing.

Clinical Studies: Chest x-ray: normal. Spirometry: showed postbronchodilator FEV_1 68% (score 2), with a 20% change in FEV_1 (score 2). During follow-up 3 months later, she was still on daily low-dose inhaled corticosteroids, with daily bronchodilator use (score 2).

Diagnosis: Latex-induced occupational asthma.

Impairment Rating: Asthma impairment score: 6 based on spirometry results and medication use; 26%-50% impairment of the whole person.

Comment: Individual was given a work restriction to avoid all future exposure to natural rubber latex because of latex allergy and asthma.

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Class 4 51%-100% Respiratory Impairment
Measured FVC: ≤ 50% of predicted
or
Measured FEV_1: ≤ 40% of predicted
or
Dco: ≤ 40% of predicted
or
$\dot{V}o_2max$: < 15 mL/(kg·min) or < 1.05 L/min or < 4.3 METS

Example 5-9
51% to 100% Impairment Due to Asthma

Subject: 40-year-old man.

History: Golf course groundskeeper for 15 years; lifelong asthma. 2 years' increasing dyspnea with mild exertion; intermittent cough. Nonsmoker. No symptom improvement over weekends. Has been on at least 20 mg of prednisone per day for past year (score 4).

Physical Exam: Height: 180 cm (5 ft 11 in); weight: 70 kg (154 lb). Diffuse expiratory wheezing over entire chest. No clubbing, cyanosis, or lower extremity edema. Cardiac examination: no air trapping.

Clinical Studies: Chest radiograph: no cardiopulmonary disease. Post bronchodilator FVC (L): observed 2.94; predicted 5.2 observed/predicted 57%; post bronchodilator FEV_1 (L): observed 1.16; predicted 4.29 observed/predicted 27% (score 4); change post bronchodilator 22% (score 2). FEV_1/FVC: observed 39%. Methacholine challenge test: not performed; severe baseline obstruction.

Impairment Rating: Asthma score: 10 (Tables 5-9 and 5-10); 51% to 100% impairment of the whole person.

Comment: Pulmonary function studies demonstrate a significant response to bronchodilators but persistent severe airway obstruction. The persistent FEV_1 percentage ≤ 50% of predicted with prolonged use of daily oral prednisone would in itself result in class 4 impairment rating for asthma. Severe symptoms require frequent oral steroids.

Example 5-10
51% to 100% Impairment Due to Emphysema

Subject: 62-year-old man.

History: Bookkeeper in vegetable-processing plant for 38 years; 10 years' gradual shortness of breath: smoked 2.5 packs of cigarettes per day for 50 years (125 pack-years); quit 6 months ago. No other disorders or exposure to hazardous dusts, chemicals, or fumes.

Current Symptoms: Severe dyspnea; unable to perform activities of daily living (driving to/from work, walking on level ground, self-dress). Occasional nonproductive cough; no wheezing, chest pain, or hemoptysis.

Physical Exam: Height: 180 cm (5 ft 11 in); weight: 69.5 kg (153 lb). Distant breath sounds; no crackles or wheezes.

Clinical Studies: Chest radiograph: hyperinflated lungs; pulmonary parenchyma vascular attenuation. FVC (L): observed 2.94; predicted 4.82; observed/predicted 61%. FEV_1 (L): observed 1.16; predicted 3.75; observed/predicted 31%. FEV_1/FVC: 39%. Dco: observed 12.87; predicted 34.5; observed/predicted 37%. $\dot{V}o_2max$: 10 mL/kg/min.

Diagnosis: Emphysema.

Impairment Rating: 51% to 100% impairment of the whole person.

Comment: Severe emphysema; unlikely to perform any significant exertion without hypoxia.

5.11 Respiratory Impairment Evaluation Summary

See Table 5–13 for an evaluation summary for the assessment of permanent impairment due to repiratory disorders.

Table 5-13 Repiratory Impairment Evaluation Summary

Disorder	History, Including Selected Relevant Symptoms	Examination Record	Assessment of Respiratory Function
General	Respiratory symptoms (eg, cough); general symptoms Impact of symptoms on function and ability to do daily activities; prognosis if change anticipated Review medical history	Comprehensive physical examination; detailed respiratory system assessment	Data derived from relevant studies (eg, pulmonary function tests)
Obstructive Disorders	Dyspnea; cough; sputum production; infections; medication use; exercise tolerance	Note breath sounds, wheeze, loud P_2, jugular vein distention, right heart prominence	Pulmonary function: spirometry, lung volumes, diffusing capacity, methacholine challenge, radiographs
Restrictive Disorders	Dyspnea; cough; fatigue; sputum; exercise tolerance	Chest wall excursion; crackles; clubbing	Pulmonary function: spirometry, lung volumes, diffusing capacity, imaging studies
Cancer	Exercise tolerance; dyspnea; chest pain; fatigue; weight loss; tobacco use; environmental exposures	Chest wall excursion; crackles; clubbing; adenopathy	Bronchoscopy; pulmonary function tests; biopsy

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	End-Organ Damage	Diagnosis	Degree of Impairment
	Include assessment of sequelae, including end-organ damage and impairment	Record all pertinent diagnosis(es); note if they are at maximal medical improvement; if not, discuss under what conditions and when stability is expected	Criteria outlined in this chapter See Table 5-12
	Assess relevant organs (eg, cardiac function, cor pulmonale)	Asthma; chronic bronchitis and emphysema; other obstructive diseases	See Table 5-12 for asthma See Tables 5-9 and 5-10
	Assess cardiac function	Idiopathic pulmonary fibrosis; asbestosis; pneumoconiosis; chest wall disorders; others	See Table 5-12
	Assess other organ function; signs of metastases	Squamous, adeno, small cell, etc	See Table 5-11

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4

American Thoracic Society
MEDICAL SECTION OF THE AMERICAN LUNG ASSOCIATION

Single-breath Carbon Monoxide Diffusing Capacity (Transfer Factor)

Recommendations for a Standard Technique—1995 Update

THIS OFFICIAL STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS ADOPTED BY THE ATS BOARD OF DIRECTORS, JULY 1995.

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BACKGROUND

There has been growing interest in standardizing lung function tests to improve reproducibility and make results more comparable from laboratory to laboratory (1–5). In 1987 the American Thoracic Society (ATS) Committee on Laboratory Proficiency Standards undertook a project to identify and standardize measurement of the carbon monoxide diffusing capacity (D_{LCO}) in an effort to reduce test variability. This resulted in official ATS recommendations for the single-breath D_{LCO} technique, which is the technique most commonly used (6). Since 1987 several new developments in D_{LCO} equipment and computational approaches have occurred. Also, the European Respiratory Society (ERS) and the British Thoracic Society have recently issued separate recommendations regarding D_{LCO} standardization (7, 8). These events prompted the ATS Committee on Laboratory Proficiency Standards to review its original recommendations and produce this 1995 update.

D_{LCO} is a measurement of carbon monoxide (CO) transfer from inspired gas to pulmonary capillary blood. This transfer is a complex phenomenon involving the distributional relation of alveolar ventilation to alveolar capillary perfusion, the actual CO transfer properties of the alveolar capillary interface, the capillary volume, the hemoglobin concentration, and the reaction rates between CO and hemoglobin (9–16). Because this process involves more than just diffusion, the measurement of CO uptake is more properly referred to as "CO transfer factor" (7). However, "carbon monoxide diffusing capacity" (D_{LCO}) is the term more commonly used in North America and, therefore, the term used in this document.

The approaches to measuring D_{LCO} include rebreathing, steady state, and a variety of single-breath techniques (7, 10, 16, 17). However, the 10-s single breath-hold technique is still the most commonly used technique in clinical laboratories. Therefore, as in 1987, the committee has restricted this document to issues concerning this method.

Using a single value to summarize individual CO uptake properties of millions of lung units is an inherent limitation in measuring and interpreting D_{LCO}. Even in normal lungs, CO uptake differs between the basilar and apical regions of the lung as a result of gravitational effects on regional blood flow and blood volume (18, 19). Regional differences may become even more pronounced in a number of disease states. Nevertheless, measuring an "overall" CO uptake by the single-breath technique has proved useful in assessing a variety of lung abnormalities that impair alveolar capillary gas transport (Table 1). Moreover, in many diseases, the magnitude of abnormalities in D_{LCO} has been shown to correlate with disease severity and with direct measurements of arterial blood oxygenation, especially during exercise (7, 20–26).

The complexity of the process reflected in the single-breath measurement of CO uptake means that considerable test variability can be expected. The magnitude of interlaboratory variability in D_{LCO} attributable to variations in test technique (breathing maneuvers, timing, methods of gas analysis, and computational techniques) has not been clearly summarized, but Clausen and associates (27) reported an interlaboratory coefficient of variation of 12.7% for D_{LCO} in comparison with 3.4% for FVC. Kan-

This statement was prepared by the Committee on Proficiency Standards for Clinical Pulmonary Laboratories. Members of the Committee were: Robert O. Crapo, M.D., Chair; John L. Hankinson, Ph.D.; Charles Irvin, Ph.D.; Neil R. MacIntyre, M.D.; Karen Z. Voter, M.D.; Robert A. Wise, M.D.

Subcommittee: Neil R. MacIntyre, M.D., Chair; Robert O. Crapo, M.D.; Brian Graham, Ph.D.; Karen Z. Voter, M.D.

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TABLE 1

PROCESSES ASSOCIATED WITH ALTERATIONS IN D_{LCO}

Decreases in D_{LCO}
Obstructive lung diseases
Emphysema
Cystic fibrosis
Parenchymal lung diseases
Interstitial lung disease
Caused by fibrogenic dusts, e.g., asbestosis
Caused by biologic dusts, e.g., allergic alveolitis
Drug reactions, e.g., amiodarone, bleomycin
Idiopathic
Sarcoidosis
Pulmonary involvement in systemic diseases
Systemic lupus erythematosus
Progressive systemic sclerosis
Mixed connective tissue disease
Rheumatoid arthritis
Dermatomyositis-polymyositis
Wegener's granulomatosis
Inflammatory bowel disease
Cardiovascular diseases
Acute myocardial infarction
Mitral stenosis
Primary pulmonary hypertension
Pulmonary edema
Acute and recurrent pulmonary thromboembolism
Fat embolization
Other
Diseases associated with anemia
Chronic renal failure
Chronic hemodialysis
Marijuana smoking
Acute and chronic ethanol ingestion
Freebasing cocaine
Cigarette smoking
Bronchiolitis obliterans with organizing pneumonia (BOOP)
Increases in D_{LCO}
Diseases associated with polycythemia
Pulmonary hemorrhage
Diseases associated with increased pulmonary blood flow such as left-to-right intracardiac shunts
Exercise

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galee and Abboud (28), in a study of one individual tested in 22 different laboratories over 13 yr, found D_{LCO} to vary from 28.7 to 41.7 ml CO/min/mm Hg. In a study in six London laboratories, Saunders (29) showed D_{LCO} values in two individuals ranging from 10.5 to 20.4 ml CO/min/mm Hg, and a more recent study by Wanger and Irvin (30) on five individuals in 13 laboratories showed individual D_{LCO} values ranging from 20.6 to 54.2 ml CO/min/mm Hg. Using computation schemes chosen from published methods, Morris and Crapo (31) demonstrated that D_{LCO} could vary by as much as 41% based on the method of computation alone. Gas analyzer inaccuracy introduces yet another source of variability. In a study of 11 laboratories, Cotes (32) found that errors in gas analysis can change D_{LCO} by 53 to 125%. In a follow-up study, Chinn and colleagues (33) found that gas analysis errors had been reduced but not eliminated. Finally, wide variability in D_{LCO} reference equations affects the percent of predicted values and may significantly affect interpretation (17, 34–35). Although the 1987 standards and technical improvements have likely reduced variability, the potential for large variations in measured D_{LCO}, predicted D_{LCO}, and percent predicted D_{LCO} still exists.

This revision will not substantially change the 1987 recommendations for equipment, calibration, and test technique issues, although they are reviewed. Our goals in this revision were to: (*1*) clarify areas of potential confusion, particularly areas where ERS (7) recommendations differ; and (*2*) address technological developments with potential to reduce D_{LCO} variability. For example, new technology allows CO and tracer gas concentrations to be monitored continuously, eliminating the need to collect gas in a sample bag during the single-breath technique (36–38). Continuous monitoring of flow and gas concentrations also permits new analytic methodologies to be developed. For example, the use of a three-equation computation method analytically accounts for variations in inspiratory and expiratory flow rather than relying on empiric corrections of the measured breath-hold time (36, 37, 39). Another example of a new analytic methodology is the technique of calculating D_{LCO} by eliminating the breath-hold and analyzing CO uptake continuously throughout a slow, controlled expiration (40, 41). Reference values and clinical research demonstrating improved diagnostic sensitivity and/or specificity are not yet available for any of these new analytic approaches. The committee encourages continuing investigation of new analytic methods but is not prepared to recommend that they replace the current single-breath technique in clinical testing at the present time. Similarly, the committee feels that testing under conditions other than with a subject sitting at rest (e.g., testing during exercise or in the supine position [42–44]) needs additional clinical research before widespread use can be recommended.

Standardization is not synonymous with truth. It is certainly not immutable. Standardizing technical issues provides a framework to allow better comparisons between measured values and reference values as well as better comparisons between laboratories. When possible, scientific information was used to guide the committee's decisions. When scientific information was not available, we made arbitrary decisions to complete the recommendations. We expect to update the recommendations as scientific studies become available.

DEFINITIONS AND ABBREVIATIONS

COHb—Carboxyhemoglobin concentration in percent (%).

CV—Coefficient of variation (standard deviation/mean value) × 100.

D_{LCO}—Carbon monoxide diffusing capacity; known as the transfer factor (T_{LCO}) in Europe. Conventional units are ml CO (STPD)/min/mm Hg; SI units are mmole CO/min/kPa. D_{LCO} in conventional units equals 2.986 × D_{LCO} in SI units.

D_L/V_A—Carbon monoxide diffusing capacity per unit of alveolar volume. In Europe, this is known as T_L/V_A. Conventional units are ml CO (STPD)/min/mm Hg/L (BTPS); SI units are mmoles CO/min/kPa/L (BTPS).

D_M—Membrane diffusing capacity (ml CO [STPD]/min/mm Hg).

F_{I_x}—Fraction of inspired gas, "x."

F_{A_x}—Fraction of "x" in the alveolar gas. An additional modifier may be added to denote time (e.g., $F_{ACO,0}$ = alveolar fraction of CO at time zero; $F_{ACO,t}$ = alveolar fraction of CO at time t).

FEV_1—Forced expiratory volume in 1 s.

FVC—Forced vital capacity.

Hb—Hemoglobin concentration in g/dl.

P_{AO_2}—Alveolar oxygen pressure in mm Hg.

P_B—Barometric pressure in mm Hg.

P_{H_2O}—Water vapor pressure in mm Hg.

P_{IO_2}—Inspired oxygen pressure in mm Hg.

ATPD—Ambient conditions and dry (ambient temperature, ambient P_B, P_{H_2O} = 0 mm Hg).

ATPS—Ambient conditions saturated with water vapor (ambient temperature, ambient P_B, P_{H_2O} reflecting saturation with water vapor at ambient temperature).

$_{BTPS}$—Body conditions (normal body temperature [37° C], ambient P_B. P_{H_2O} reflecting saturation with water vapor at 37° C [47 mm Hg]).
$_{STPD}$—Standard conditions (temperature = 0° C, P_B = 760 mm Hg, P_{H_2O} = 0 mm Hg).
t—Breath-hold time in seconds.
TLC—Total lung capacity.
θ—Specific uptake of CO (ml CO [STPD]/min/mm Hg/ml blood).
Tr—Tracer gas, a relatively insoluble and biochemically inert gas used to calculate V_A from its dilution in alveolar gas.
RV—Residual volume.
V_A—Alveolar volume during the test in liters. Conditions (BTPS or STPD) should be specified (e.g., V_A BTPS).
VC—Vital capacity.
V_C—Pulmonary capillary blood volume (ml).
V_D—Dead-space volume in liters. Dead space is of three types: anatomic V_D—dead-space volume of the patient's conducting airways; instrument V_D—dead-space volume of the instrument, including mouthpiece, tubing, and connectors; and sample bag V_D—dead-space volume of an alveolar sample bag.
V_I—Inspired volume. The volume of test gas inspired as part of the D_{LCO} test in liters. Conditions (ATPS, ATPD, BTPS, STPD) should be specified (e.g., V_I STPD).
V_S—Volume of the expired sample gas in liters.

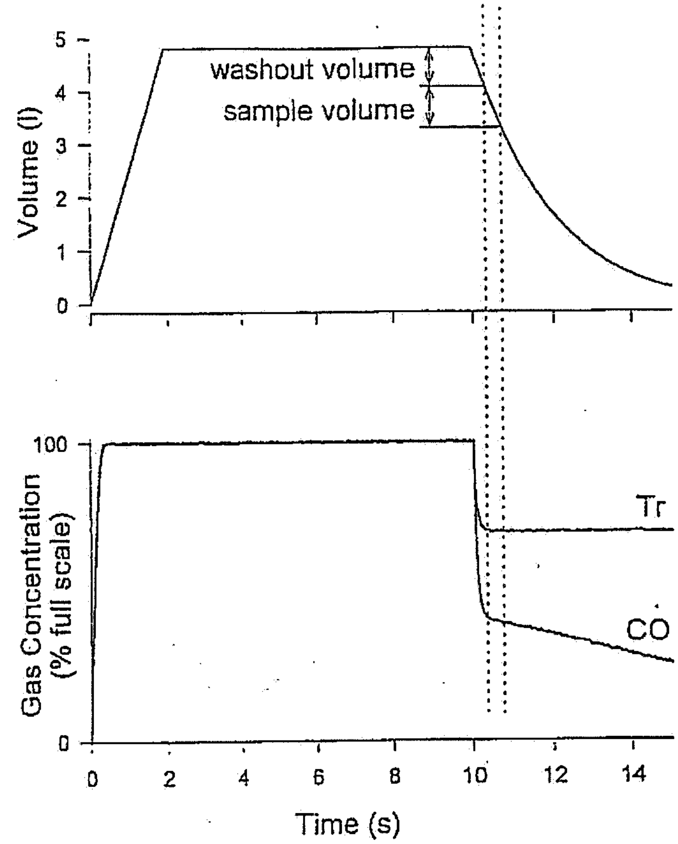

Figure 1. A schematic of lung volume versus time (*upper panel*) and carbon monoxide (CO) and tracer gas (Tr) concentrations versus time (*lower panel*) during a standard D_{LCO} measurement using a continuous analyzer. The dotted lines indicate when the alveolar sample occurs.

GAS ANALYZERS AND GENERAL EQUIPMENT

System Design

Descriptions of the apparatus and general instructions for performing the single-breath diffusing capacity maneuver are available elsewhere (2–5, 7, 17, 45, 46). Equipment in clinical use varies widely in complexity, but the basic principles are the same. All systems have a source of test gas (bag-in-box, spirometer, compressed gas cylinder), a method for measuring inspired and expired volume over time (spirometers with kymographs, pneumotachometers near the mouthpiece or near a bag-in-box), and gas analyzers (single-sample analyzers or continuous analyzers). Single-sample gas analyzer systems usually display volume over time (Figure 1, *upper panel*). Continuous gas analyzer systems may also provide a continuous tracing of CO and tracer gas concentrations (Figure 1, *lower panel*).

Equipment Requirements

Minimum standards for equipment include (Table 2):

1. Volume measurement accuracy should be the same as that established by the ATS for spirometry (47); that is, ± 3% volume accuracy over an 8-L volume range, with test gases present in concentrations likely to be encountered during D_{LCO} tests. Some pneumotachometer devices are sensitive to different gas concentrations. These devices should maintain the required volume accuracy when test gases are used (e.g., when they are inhaled or exhaled by a subject) (48).
2. Gas analyzer accuracy is important in some circumstances, such as measuring CO "back pressure." However, in calculating D_{LCO} only the *ratios* of CO and the tracer gas are used, and the accuracy of the gas analyzers is not as important as the ability to provide a linear output. Linearity should be within 1% of full scale (i.e., once the analyzers have been adjusted to zero with no test gas present and then set to an arbitrary full scale value at the test gas concentrations, the combined effects of zero drift, gain drift, and system nonlinearity on measurements of known dilutions of test gas should be no more than 1% of full scale). The gas analyzers should be stable so linearity is maintained over the test interval. Manufacturers are encouraged to provide a display of the gas concentrations measured by the analyzers so linearity can be confirmed.
3. Circuit resistance should be less than 1.5 cm H_2O/L/s at 6 L/s flow. If a demand flow regulator is used on a compressed test gas cylinder, the maximal inspiratory pressure required for 6 L/s inspiratory flow through both circuit and valve should be less than 10 cm H_2O.
4. The timing device in the D_{LCO} apparatus should be accurate to within 1% (100 ms over 10 s). The timing technique used for calculation should be identified. If an instrument provides automatic data computation, the accuracy of breath-hold time computation should be documented.
5. Dead space for both inspired test gas and the alveolar sample should be known, and their role in all data computation algorithms identified and documented. The dead space of the valve and mouthpiece should total less than 0.100 L.
6. If CO_2 and/or H_2O will interfere with gas analyzer performance, they must be removed from the test gases before passage through the gas analyzers. Water is commonly absorbed by anhydrous $CaSO_4$ or by other products. Selectively permeable tubing can also be used to remove water. Water-vapor permeable tubing has a limited life expectancy. The calculation of D_{LCO} may be significantly affected when such tubing fails to properly equilibrate water vapor. Manufacturers should provide a replacement schedule for water-vapor permeable tubing and a method for checking its function. Users of such tubing should be aware of the problem and have a plan for

TABLE 2

EQUIPMENT SPECIFICATIONS

Volume accuracy	± 3% accuracy over an 8 L volume using test gases
Gas analyzers	Linear from zero to full span within ± 1% of maximal value over duration of test
Circuit resistance	< 1.5 cm H_2O/L/s at flow of 6 L/s
Demand valve sensitivity (if compressed gas source used)	< 10 cm H_2O required for 6 L/s flow through valve and circuit
Timer	± 1.0% over 10 s
Apparatus dead space	< 0.1 L

replacing the tubing at appropriate intervals and for checking the tubing function. A monthly check of tubing function is recommended. One method of checking water vapor permeable tubing is to compare gas concentration measurements made with both dry and humidified test gas. Absorption of CO_2 can be achieved with either $Ba(OH)_2$ or NaOH. Both generate H_2O when combining with CO_2. Therefore, if a CO_2 absorber is used, it must precede the water absorber in the gas analyzer circuit.

7. The system must be leak-free. This is particularly important for DLCO systems that aspirate gas samples at subatmospheric pressure through the gas analyzers (rather than blowing the gas samples at supra-atmospheric pressure). When samples are aspirated, leaks in tubing, fittings, and other locations allow room air to be drawn into the gas circuit, diluting the sample and reducing the concentrations of test gases.

Equipment Quality Control (Table 3)

1. Each day:
   a. Volume calibration with a calibrated 3-L syringe (47–49).
   b. Leak testing (47, 49).
2. Each quarter:
   a. Gas analyzer linearity should be assessed. A straightforward approach is to measure known serial dilutions of test gas, similar to the methods suggested for gas chromatography by Okubo and Lenfant (50) and recommended by the ERS (7).
   b. The timer should be assessed for accuracy (49).
   c. Standard subject(s) should be tested to assure overall stability of the system. Standard subjects are healthy nonsmokers (e.g., healthy laboratory personnel). If the DLCO in a standard subject varies more than 10% from known previous values, the test should be repeated. If the repeat test confirms the finding, the DLCO system should be evaluated carefully for the possibility of leaks, nonlinear analyzer function, volume and time inaccuracy, etc. When sufficient data on a standard individual are obtained, laboratories may choose to establish their own outlier criteria to serve as indicators of potential problems with their DLCO systems.
3. Records of equipment checks and standard subject tests should be dated, signed, and kept in a laboratory log book. Manufacturers are encouraged to provide software options for quality control measurements and quality control data management.

TABLE 3

EQUIPMENT QUALITY CONTROL

Volume accuracy and leak testing	Tested daily
Gas analyzer linearity	Tested quarterly
Timer	Tested quarterly
Tests on laboratory personnel	Tested quarterly

Infection Control

The major goal of infection control is to prevent the transmission of infection to patients and staff during pulmonary function testing. Infection may be transmitted by two modes:

1. *Direct contact.* Through direct contact with potential pathogens, there is the potential for transmission of upper respiratory disease, enteric infections, and blood-borne infections. Although infection with hepatitis and HIV are unlikely via saliva, the possibility exists when there is hemoptysis, open sores on the oral mucosa, or bleeding gums. The most likely surfaces for contact are mouthpieces and the immediately proximal surfaces of valves or tubing.
2. *Indirect contact.* Contaminated aerosol droplets have the potential for transmitting tuberculosis, various viral infections and possibly opportunistic infections and nosocomial pneumonia to susceptible patients. Mouthpieces and proximal valves and tubing are likely candidates for contamination by aerosols.

Pulmonary function equipment has not been directly implicated in the transmission of infections. However, there is indirect evidence that infection may be transmitted during pulmonary function testing. Organisms from the respiratory tract of test subjects have been recovered from mouthpieces and from the proximal surfaces of tubing through which subjects breathe (51, 52). This does not seem to pose an appreciable threat to patients with competent immune systems, although there is some potential for cross-contamination. There is one case report of tuberculosis skin test conversion after exposure to a spirometer used to test a patient with documented tuberculosis (53). There is also circumstantial evidence implicating contaminated pulmonary function equipment in the increasing prevalence of infections due to pseudomonas (especially *Pseudomonas cepacia*) among cystic fibrosis patients at one center (54). Finally, it is well documented that community and hospital water supplies can be contaminated with legionella, mycobacteria, and pseudomonas organisms (55–57). Thus, there is a potential for patients and health care workers to deposit microorganisms onto pulmonary function testing circuit surfaces (including mouthpieces, nose clips, tubing, and any internal or external machine surface); these microorganisms could subsequently come into direct or indirect contact with other patients.

Concerns for the protection of immunocompromised hosts, along with increased public and provider awareness of hospital infection control issues over the past decade have led many laboratory directors to use in-line filters routinely as a means of reassuring patients and laboratory personnel that adequate consideration has been given to protection (58, 59). The extent to which in-line filters affect the measurements needed to calculate DLCO is undocumented. One study has shown that a low impedance barrier device did not have a significant impact on spirometric indices such as the FVC and FEV_1 (60).

Recommendations:

1. Prevention of infection transmission to technicians exposed to contaminated equipment surfaces can be accomplished through proper hand washing or use of barrier devices (latex gloves). To avoid technician exposure and cross-contamination, hands must be washed immediately after direct handling of mouthpieces, tubing, breathing valves, or interior equipment surfaces. Gloves must be worn when handling potentially contaminated equipment if there are any open cuts or sores on technicians' hands. Hand washing must always be performed between patients. Indications and techniques for hand washing during pulmonary function testing have recently been reviewed by Tablan and colleagues (61).

2. To avoid cross-contamination, reusable mouthpieces, breathing tubes, valves, and manifolds should be disinfected or sterilized regularly. Mouthpieces, nose clips, and any other equipment coming into direct contact with mucosal surfaces should be disinfected or sterilized after each use. The optimal frequency for disinfection or sterilization of tubing, valves, or manifolds has not been established. However, any equipment surface with visible condensation from expired air must be disinfected or sterilized before reuse.
3. In settings where tuberculosis or other diseases spread by droplet nuclei are likely to be encountered, proper attention to engineering controls, such as ventilation, air filtration, or ultraviolet decontamination of air, must be used to prevent disease transmission (62).
4. Special precautions must be taken when testing patients with hemoptysis, open sores on the oral mucosa, or bleeding gums. Tubing and breathing valves must be decontaminated before reuse, and internal device surfaces must be decontaminated with accepted disinfectants for blood-transmissible agents.
5. Extra precautions may be undertaken for patients with known transmissible infectious diseases. Possible precautions include: (a) reserving equipment for the sole purpose of testing infected subjects; (b) testing patients at the end of the day to allow time for disassembly and disinfection; and (c) testing patients in their own room or in rooms with adequate ventilation and easily cleaned surfaces.
6. Many devices currently used to measure D_{LCO} incorporate complex valving mechanisms that are located proximal to breathing tubes. These are often difficult to disassemble and disinfect between subjects. In settings where routine disassembly of these mechanisms is not possible, in-line filters may be effective in preventing equipment contamination (59). The economy of using in-line filters as compared with tubing and valve changes will depend on the equipment in use. If an inline filter is used, the measuring system must meet the minimal recommendations listed above for system accuracy, flow resistance, back pressure, and dead space with the filter installed. Moreover, the interpretation of results should allow for the possibility that the filter might affect equipment performance. Appropriate adjustments must be made for additional dead space due to a filter, and equipment must be calibrated with a filter installed.
7. Manufacturers of D_{LCO} equipment are encouraged to design instrumentation that can be easily disassembled for disinfection or find other solutions to hygiene concerns.

STANDARDIZATION ISSUES

The issues addressed by the committee are categorized as technique factors, calculation factors, and interpretation factors. Each issue is summarized and discussed, and a recommendation for a standard approach given.

Technique Factors

Patient conditions for measurement. In general, conditions that may affect pulmonary capillary blood volume and, therefore, measured D_{LCO} should be avoided. They include exercise and heavy meals.

D_{LCO} increases with a change from the seated to the supine position and decreases from the seated to the standing position (42–46, 63). Estimates of the magnitude of the change in D_{LCO} with position change are variable (e.g., 5 to 30% from sitting to supine) (42, 43). D_{LCO} also increases with exercise (41–44, 64).

Recommendations. Before beginning the test, the maneuvers should be demonstrated and the subject carefully instructed. The subject should be seated for at least 5 min before testing and remain seated throughout the test procedure. The test should be performed at least 2 hr after a light meal and with the subject having refrained from recent strenuous exercise.

Inspiratory maneuver. Once the mouthpiece is in place, four to five tidal volumes are recorded to determine a regular end-expiratory baseline. The D_{LCO} maneuver then begins with exhalation to residual volume (RV). At RV the subject's mouthpiece is connected to a source of test gas and the subject inhales rapidly to total lung capacity (TLC). The volume of test gas inhaled is V_I. D_{LCO} should be measured near TLC. The 1987 ATS recommendation was that V_I be > 90% of the largest previously measured vital capacity. The ERS recommends that the V_I should be adequate to achieve 90 to 95% TLC (7).

Inspiratory time in healthy subjects averages 1.5 to 2 s (46, 65). In healthy subjects, 95% of inspiratory times are less than 2.5 s (R. O. Crapo, personal communication). In patients with moderate to severe airflow obstruction ($FEV_1/VC < 0.5$), inspiratory times average about 2 s, with 95% less than 4 s. If the time of inspiration is increased to one half of the breath-hold time (approximately 5 s), the D_{LCO} is reduced by 13% when breath-hold time is measured using the Ogilvie technique (*see* CALCULATIONS) (46, 65).

Calculating inspiratory time is difficult when the beginning and end of inspiration are not clear. Until more is known, the committee recommends that the back extrapolation technique be used to establish time zero because it is a standard technique in spirometry (1, 47, 66). Since the end of inspiration may be less readily identified, the committee recommends the time when 90% of the V_I has been inspired as a reasonable end point for the purpose of meeting the inspiratory time criteria only.

The rate of inspiration will depend in part upon the resistance of the inlet circuit and the demand valve characteristics (if present). If inlet circuit resistance is too high, the demand valve too insensitive/unresponsive, or if a patient has a high central airway resistance, a rapid inspiratory maneuver may effectively be a Muller maneuver (inspiratory effort against a closed airway), which will falsely increase D_{LCO} (67–69).

Recommendations. The inspiration should be rapid. Ninety percent of V_I should be inspired in less than 2.5 s in healthy subjects and in less than 4.0 s in patients with moderate to severe airway obstruction. The V_I should be at least 90% of the largest previously measured vital capacity, both expressed at BTPS conditions.

Condition of the breath-hold. Valsalva (expiratory efforts against a closed airway) and Muller maneuvers (inspiratory efforts against a closed airway) during the breath-hold will decrease and increase D_{LCO}, respectively (67–69). The 1987 ATS recommendation was to have subjects relax against a closed glottis or valve (6). The rationale was that it was felt this technique would produce the least variation in intrathoracic pressure. This maneuver, however, may be more difficult to perform than simply having the subject voluntarily maintain full inspiration using only the minimal effort necessary.

Recommendation. After inspiring the test gas, the subject should either try to relax against a closed glottis or a closed valve during the breath-hold or else maintain a full inspiratory position without straining. Excessive positive or negative intrathoracic pressure (i.e., obvious Valsalva or Muller maneuvers) should be avoided during breath-hold.

Expiratory maneuver. Recommendation. At the end of the breath-hold period, the expiratory maneuver should be smooth, without hesitation or interruption. Sample collection time should not exceed 4 s.

Washout volume. During expiration, a volume of gas must be expired and discarded to clear anatomic and mechanical dead space before the alveolar sample is collected (17, 46). The Intermountain Thoracic Society (ITS) (3) and the ERS (7) both recommend washout volumes of 0.75 L. Ogilvie and colleagues (46) reported a 10% increase in D_{LCO} as the washout volume increased from 1.0 to 2.5 L. Huang and MacIntyre (38) demonstrated with a continuous analyzer that an 0.75 L washout volume was appropriate in more than 90% of patients referred to a pulmonary function laboratory.

Recommendation. In a single-sample system, the washout volume should be 0.75 to 1.0 L. If the patient's vital capacity is < 2.00 L, the washout volume may be reduced to 0.50 L; any such change should be noted in the report. If a continuous gas analyzer system is used, computerized or manual inspection of the expired CO and tracer gas curves may be used to adjust washout volume to assure dead space clearance (Figure 1).

Sample collection volume. Sample volume depends on analyzer requirements as well as assurance that a representative alveolar sample is obtained. The current ERS (7) and ITS (3) recommendations for sample volume are 0.50 to 1.00 L. The Epidemiologic Standardization Project (ESP) recommends a 1-L sample (0.50 L if the vital capacity is < 2.00 L). Continuous gas analyzers can determine alveolar CO concentrations on much smaller volumes (38).

Ogilvie and colleagues (46) recommended that the duration of the alveolar collection be < 2 to 3 s. Kanagami and associates (65) suggested that the total collection time (washout and alveolar sample collection) not exceed 4 s. With the Ogilvie method of calculating breath-hold time (*see* CALCULATIONS), D_{LCO} increases with increased sample collection time (46, 65). This effect may not be seen with the method by Jones and Meade (70), ESP (2) timing method, or the three-equation technique (36, 37).

Recommendation. With single-sample D_{LCO} systems, a sample volume of 0.50 to 1.00 L should be collected in less than 4 s. If continuous analyzers are used, computerized or visual inspection of the expired CO and tracer gas curves may be used to adjust sample volume to assure an appropriate alveolar sample (38).

Inspired oxygen pressure and alveolar P_{O_2}. Alveolar P_{O_2} (P_{AO_2}) and measured D_{LCO} are inversely related. Since P_{AO_2} fluctuates over the ventilatory cycle, the consensus in the European community (7) is that a more stable P_{AO_2} during the D_{LCO} maneuver is achieved with a test gas fraction of inspired oxygen (F_{IO_2}) of 0.17 and variability in measured D_{LCO} should therefore be reduced. In the United States, an F_{IO_2} of 0.21 is generally used, although some systems use test gas mixtures containing CO and He with "balance air." If such a mixture contains about 10% helium, 0.3% CO, and balance air, the F_{IO_2} will be about 0.19. When using other tracer gases, the test gases may constitute less than 1% of the total gas mixture. No current data are available to suggest a preference for the European ($F_{IO_2} = 0.17$) or American ($F_{IO_2} = 0.21$) methods.

Measured D_{LCO} will increase as altitude increases (and P_{IO_2} and P_{AO_2} decrease). Kanner and Crapo (71) demonstrated that commonly encountered alveolar oxygen pressures at higher altitudes will cause D_{LCO} to increase an average of 0.35% for each mm Hg decrease in alveolar P_{O_2}. This finding was confirmed by Gray and associates (72) using a hypobaric chamber to simulate altitude changes when they found an average D_{LCO} increase of 0.31% per mm Hg decrease in P_{IO_2}. Both groups argue that increasing test gas P_{IO_2} is an acceptable way to adjust D_{LCO} for altitude.

The use of supplemental oxygen will alter P_{AO_2} and therefore D_{LCO}. The magnitude of the effect and the method of adjusting D_{LCO} in individual patients using supplemental oxygen are unknown and this is an area where further research is clearly needed. Until more is known, it is probably best to measure D_{LCO} with subjects breathing room air as long as it is considered to be clinically safe.

Recommendations. Until more information is available, the test gas in the American community should contain 21% oxygen at sea level. It is recognized that this is controversial and differs from the standard practice in the European community. At altitudes other than sea level, either the test gas F_{IO_2} can be adjusted accordingly (adjust F_{IO_2} to produce a P_{IO_2} of 150 mm Hg) *or*, if the test gas contains 21% oxygen, the results should be adjusted for altitude or sample bag P_{O_2} (P_{AO_2}) (71, 72) as part of the interpretation (*see* INTERPRETING THE RESULTS).

Supplemental oxygen should be discontinued at least 5 min before beginning the test. If this cannot be done safely, the interval of time off oxygen should be adjusted appropriately and the resulting D_{LCO} interpreted with caution (see previous comments on the effects of alveolar P_{O_2}).

Interval between tests. Although Ogilvie and colleagues (46) demonstrated essentially complete elimination of test gas in 2 min in three healthy subjects and one emphysematous subject, it is reasonable to expect that a longer interval may be required in some patients with severe maldistribution of ventilation. Johns and associates (73) found no difference between the first and second tests in 129 patients when the interval between tests was 4 min.

Recommendation. At least 4 min should be allowed between tests to allow adequate elimination of test gas from the lungs. The subject should remain seated during this interval. In patients with obstructive airway disease, several deep inspirations during this period may help clear test gases more effectively. If continuous monitoring of expired gas concentrations is available, the washout of tracer gas from the previous test may be confirmed by observing end-tidal gas concentrations before beginning the next test. Subsequent tests should not begin until the end-tidal tracer gas concentration is less than 1% of full scale.

Miscellaneous factors. There may be diurnal variation in D_{LCO}. Cinkotai and Thomson (74) found that D_{LCO} fell progressively throughout the day. Between 9:30 A.M. and 5:30 P.M., the decrease was 1.2%/h, and from 5:30 P.M. to 9:30 P.M., the decrease was 2.2%/h. The reason for the change was not clear and was not explained by CO back pressure or changes in V_A, V_I, or breath-hold time. Frey and colleagues (75), however, explained D_{LCO}'s diurnal variation by increases in CO back pressure and by diurnal variation in hemoglobin concentration.

A 13% change in D_{LCO} during the menstrual cycle has been reported (76). The highest value was observed just before the menses and the lowest was on the third day of menses. This may reflect a hemoglobin effect.

Peavy and colleagues (77) have shown that D_{LCO} is reduced about 15% 90 min after ingestion of 15 to 30 ml of 95% ethanol. The reason for the change is unknown, and the finding has not been confirmed. However, it may reflect analyzer behavior in the presence of ethanol because similar changes have been noted in ketosis.

Cigarette smoking can have profound effects on the measurement of CO uptake. Lung pathology caused by long-term use of cigarettes is known to cause significant reductions in D_{LCO} (21, 78–83). However, there also appears to be a mild, acute, and reversible decrease in D_{LCO} during acute cigarette smoking (80–82). This acute effect is thought to be largely due to the effects on CO back pressure and the "anemia effect" due to increased carboxyhemoglobin concentration (*see* CALCULATIONS, carboxyhemoglobin and hemoglobin corrections).

Recommendations. Subjects should be asked to refrain from smoking for 24 h before the test. The time of the last cigarette smoked should be recorded. A correction for CO back pressure should be made for recent or heavy cigarette smoking (*see* CALCULATIONS, carboxyhemoglobin adjustment). Subjects should avoid alcohol for at least 4 h before testing.

Calculations

Basic formula for calculating D_{LCO}:

$$D_{LCO} = V_A\,(\text{STPD}) \times (1/t) \times [1/(P_B - 47)] \times \ln(F_{ACO,0}/F_{ACO,t}) \times 60{,}000$$

where $F_{ACO,0} = F_{ICO} \times (F_{ATr}/F_{ITr})$

and $V_A = (V_I - V_D) \times F_{ITr}/F_{ATr}$.

In these calculations volumes are in liters, breath-hold time (t) in seconds, barometric pressure (P_B) in mm Hg; 47 represents water vapor pressure at 37° C. F_{ICO}, $F_{ACO,t}$, F_{ITr}, and F_{ATr} are the fractional concentrations of carbon monoxide and the tracer gas in the inspired and alveolar gas samples, respectively. V_A is alveolar volume, V_I is inspired volume, and V_D is dead-space volume (anatomic and instrument). The factor 60,000 converts L/s to ml/min. This equation (15) is technically valid only for the breath-holding portion of the single-breath maneuver but is usually applied to the entire maneuver.

Breath-hold time—measurement and duration. Inspiration and expiration times are finite and must be considered in the calculation of breath-hold time.

Three widely used methods of measuring breath-hold time for D_{LCO} are illustrated in Figure 2. The "classic" or Ogilvie method (46) measures breath-hold time from the beginning of inspiration to the beginning of sample collection. Jones and Meade (70) proposed a second method, theoretically more accurate and reproducible than the classic method. Breath-hold time was measured to include 0.7 of the inspiratory time and 0.5 of the sample collection time. This approach computes breath-hold time based on the expected CO concentration profile in the alveolar space from a theoretical instantaneous inspiration compared with a typical pattern of inspiration. The ESP (2) recommended measuring breath-hold time from the point at which one half of V_I had been inspired to the beginning of sample collection. There is little difference in calculated D_{LCO} using either the Ogilvie or the Jones and Meade breath-hold time technique in normal subjects (84–86), but the latter method provides the least overestimation of D_{LCO} when airflow obstruction is present (87). The ESP technique produces a significantly shorter breath-hold time, and thus a larger D_{LCO} in normal subjects and patients with airflow limitation (86). The 1987 ATS recommendations (6) accepted either the Jones and Meade or Ogilvie techniques but discouraged use of the ESP technique.

A theoretically more accurate way to account for volume changes over time during inspiration and expiration is to use three separate equations for D_{LCO} during inspiration, breath-hold, and expiration (the "three-equation" technique [36, 37]). This algorithm is commercially available but its clinical advantages are not yet clear.

Recommendation. The Jones and Meade method of determining the breath-hold time is the preferred method. The start and end of inspiration is determined by extrapolation of the best-fit linear regression of volume versus time during inspiration. The technician should take care to assure that the breathing maneuver does not have stepwise changes in inspiration, breath-holding, or expiration. Breath-hold time should be between 9 to 11 s. Alternative breath-hold timing algorithms may be appropriate to maintain consistency (e.g., longitudinal studies), but these measurements should be recognized as outside ATS recommendations.

Alveolar volume, method of measurement. Because D_{LCO} reflects CO uptake from alveolar gas, a measurement of alveolar volume (V_A) is required. V_A can be calculated by adding V_I to a separately measured residual volume and using appropriate adjustments for dead space. More frequently, V_A is calculated by measuring the tracer gas dilution during the breath-hold (see below). If the tracer gas dilution method is used to calculate V_A, tracer gas properties and the various dead spaces must be considered.

The *tracer gas* should be relatively insoluble and be chemically and biologically inert. Because the tracer gas is being used

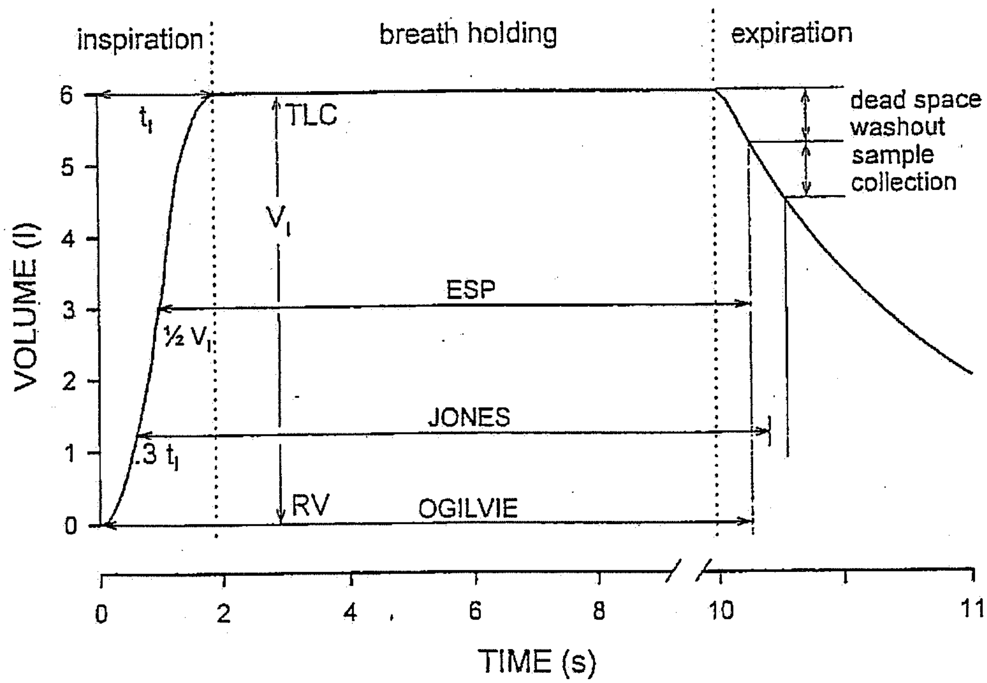

Figure 2. Schematic illustration of different methods of measuring breath-hold time for the single-breath D_{LCO}. V_I = inspired volume; t_I = time of inspiration. The Ogilvie or "classic" method (46) measures breath-hold time from the beginning of inspiration to the beginning of alveolar sample collection. The Jones and Meade method (70) includes 0.70 of inspiratory time and half of sample time. The Epidemiologic Standardization Project (2) measures breath-hold time from the time of 50% of V_I to the beginning of alveolar sample collection.

to determine the V_A from which CO uptake is occurring, its density, viscosity, and gaseous diffusivity should be similar to CO. It should approximately follow the ideal gas law and should not interfere with the measurement of CO concentration. The tracer gas should not ordinarily be present in alveolar gas (e.g., He) or be present at a known, fixed concentration (e.g., Ar). The tracer gas used most frequently is helium (He). While He meets most of the criteria, being relatively insoluble and inert, its gaseous diffusivity and viscosity are higher than air. Studies comparing single-breath He dilution lung volumes to other methods of measuring lung volumes have shown good agreement in normal subjects but underestimation of V_A in patients with obstructive lung disease (attributed to incomplete gas mixing) (2, 39). Other noble gases, including neon (Ne) and argon (Ar), have been used as tracer gases. There are also reports of using small concentrations (0.3%) of methane (CH_4) as a tracer gas (38, 42). As new tracer gases are introduced, manufacturers should demonstrate that they produce V_A and D_{LCO} values equivalent to those measured using traditional tracer gases.

Dead space occurs in three areas: instrument dead space (volume of the mouthpiece, filters [if used], and connections within the valving system), anatomic dead space (volume in the conducting airways that does not participate in gas exchange), and in single sample systems with collection bags, sample bag dead space (residual volume in the sample bag and connectors).

Calculations of V_A from single-breath tracer gas dilution must account for these dead-space volumes by subtracting both instrument and anatomic dead space from inspired volume. The calculation of V_A is thus: $V_A = F_{I_{TR}}/F_{A_{TR}} \times (V_I - \text{instrument } V_D - \text{anatomic } V_D)$. Instrument V_D should be specified by the manufacturer but may vary as the user alters the system (e.g., addition of a filter). Anatomic V_D is usually estimated from body size (88) but can vary with lung volume and breath-hold time (89, 90). The 1987 ATS recommendation (6) was to use a fixed value of 150 ml for anatomic V_D. This value, however, does not work well for small adults or children. Cotes (45) suggests an adjustment of 2.2 ml/kg body weight for anatomic V_D. If a continuous gas analyzer is used, anatomic V_D may be measured using the technique described by Fowler (90).

Sample bag dead space (sample bag V_D) dilutes the sample gas and alters the measured concentrations of expired gases. The size and direction of the error depend on sample volume (V_S), the dead-space volume of the sample bag and its connectors (sample bag V_D), and sample bag V_D gas content. Sample bag V_D could contain test gas, room air, or expired gas from a subject (after a D_{LCO} test). When sample bag V_D contains room air, the effect of sample bag V_D is to reduce the measured concentrations of expired gases. The $F_{A_{Tr}}$ term in the calculation of V_A should be adjusted for this dead space. When sample bag V_D contains room air, the adjustment is as follows (the adjustment will differ when sample bag V_D contains gases other than room air):

$$\text{Adjusted } F_{A_{Tr}} = \text{measured } F_{A_{Tr}} \times (V_S/[V_S - \text{sample bag } V_D])$$

No adjustment is required in the $F_{A_{CO,0}}/F_{A_{CO,t}}$ term because the adjustment factor occurs in both the numerator and denominator and cancels. Estimates of the potential change in D_{LCO} in existing systems when no adjustment is made for sample bag dead space range from 0.3 to 8%, depending on sample bag size and sample bag V_D (31).

Alveolar volumes calculated by the single-breath tracer gas dilution techniques or by adding V_I to a separately measured RV (after accounting for anatomic V_D) are usually comparable in normal subjects. Indeed, several investigators (91, 92) have found that differences between single-breath and closed-circuit tracer gas dilution methods were small and of little consequence in normal subjects as well as patients with mild air flow obstruction ($FEV_1/VC > 0.5$). As airflow obstruction worsens, however, impaired gas mixing and distribution during the breath-hold can lead to significantly lower values for simultaneously measured single-breath V_A than for V_A obtained by other methods (93, 94). This discrepancy can lead to substantial differences in calculated D_{LCO} in patients with airflow obstruction, depending on which measurement of V_A is used (95). If the simultaneous single-breath V_A is used, the calculated D_{LCO} could be considered as the D_{LCO} in the regions of the lung into which test gas was distributed. If the sum of V_I and a separately measured RV are used as V_A, the resulting D_{LCO} should be considered the D_{LCO} that would exist if that entire V_A had CO transfer properties similar to the average of the lung regions into which test gas was distributed (i.e., the lung regions measured by the simultaneous single-breath method of measurement of V_A).

Recommendations. Manufacturers should report instrument and sample bag dead space. Efforts should be made to reduce instrument dead space (including filters) to less than 100 ml. The instrument dead space (including sample bag) must be flushed with room air (or if membrane component of diffusion [D_M] and pulmonary capillary blood volume [V_C] are to be calculated, appropriate levels of oxygen) before the single-breath maneuver so that it will not contain expiratory gas from a previous subject. Sample bag dead space should be less than 2% of the sample volume or 10 ml, whichever is larger. An appropriate adjustment for sample bag dead space should be made to the measurement of $F_{A_{Tr}}$. The adjustment will vary depending on the gas in sample bag V_D. Anatomic dead space should be calculated as 2.2 ml per kg of average body weight expressed at ATPD conditions.

The V_A used to calculate single-breath D_{LCO} should always be determined using single-breath tracer gas dilution. Other methods of estimating V_A in the calculation of D_{LCO} are also acceptable but must be reported in addition to the single-breath method and the method of V_A measurement identified.

Inspired gas conditions. Though inspired gas is commonly assumed to be at ATPS conditions (2), this is only true in systems in which the test gas is transferred to a water-sealed spirometer before it is inspired. In most cases, test gas inspired from a bag-in-box system or through a pneumotachometer from a bag or a compressed gas cylinder with a demand valve is a dry gas (less than 10 ppm water) and thus at ATPD conditions (3). When D_{LCO} is calculated with V_I at ATPS rather than at ATPD (assuming the actual conditions are ATPD), D_{LCO} is underestimated by 3% at sea level and by 4% at 1400 m altitude (31).

Recommendation. The inspired gas conditions should be correctly determined and the proper conversion factors used (Table 4). Manufacturers should specify and document inspired gas conditions for each instrument.

CO_2 and H_2O adjustment. When V_A is measured as part of the single-breath maneuver and when gas analyzer properties require that CO_2 and H_2O be absorbed before gas analysis, the expired tracer gas and CO concentrations are artifactually increased (2). $F_{I_{CO}}$ and $F_{I_{Tr}}$ are unaffected when no CO_2 or H_2O is present in the test gas. No adjustment for the increase in $F_{A_{CO,t}}$ and $F_{A_{Tr}}$ is necessary in calculating the rate of CO uptake since the concentration factor appears in both the numerator and the denominator of the expression ($F_{A_{CO,0}}/F_{A_{CO,t}}$) and therefore cancels. An adjustment for the increase in expired tracer gas concentration ($F_{A_{Tr}}$) is necessary when it is used to calculate V_A.

Some newer systems use selectively permeable tubing to either remove water vapor completely or to equilibrate all gas samples with ambient humidity. Proper correction factors must be applied that require knowing how water vapor affects gas concentration measurements.

TABLE 4

ADJUSTMENTS TO TRACER GAS CONCENTRATIONS FOR H_2O, CO_2, AND TEMPERATURE

1. H_2O removed from sampled gas; CO_2 does not interfere with analyzers:

$$V_{A_{BTPS}} = (V_{I_{ATPD}} - V_{D_{INST}} - V_{D_{ANAT}}) \cdot \frac{F_{I_{Tr}}}{F_{S_{Tr}}} \cdot \frac{P_B}{P_B - 47} \cdot \frac{310}{273 - T}$$

$$V_{A_{STPD}} = (V_{I_{ATPD}} - V_{D_{INST}} - V_{D_{ANAT}}) \cdot \frac{F_{I_{Tr}}}{F_{S_{Tr}}} \cdot \frac{P_B}{760} \cdot \frac{273}{273 - T}$$

2. H_2O and CO_2 removed from sampled gas:

$$V_{A_{BTPS}} = (V_{I_{ATPD}} - V_{D_{INST}} - V_{D_{ANAT}}) \cdot \frac{F_{I_{Tr}}\,(1 - F_{ACO_2})}{F_{S_{Tr}}} \cdot \frac{P_B}{P_B - 47} \cdot \frac{310}{273 + T}$$

$$V_{A_{STPD}} = (V_{I_{ATPD}} - V_{D_{INST}} - V_{D_{ANAT}}) \cdot \frac{F_{I_{Tr}}\,(1 - F_{ACO_2})}{F_{S_{Tr}}} \cdot \frac{P_B}{760} \cdot \frac{273}{273 - T}$$

If no measurement of F_{ACO_2} is available then it may be assumed to be 0.05.

3. H_2O in sampled gas equilibrated to room air; CO_2 does not interfere with analyzers.
If $F_{I_{Tr}}$ is read by the analyzers, the equations are the same as #1.
If tank values (i.e., dry gas concentrations) are used for $F_{I_{Tr}}$, then:

$$V_{A_{BTPS}} = (V_{I_{ATPD}} - V_{D_{INST}} - V_{D_{ANAT}}) \cdot \frac{F_{I_{Tr}}}{F_{S_{Tr}}} \cdot \frac{P_B - P_{H_2O}}{P_B - 47} \cdot \frac{310}{273 - T}$$

$$V_{A_{STPD}} = (V_{I_{ATPD}} - V_{D_{INST}} - V_{D_{ANAT}}) \cdot \frac{F_{I_{Tr}}}{F_{S_{Tr}}} \cdot \frac{P_B - P_{H_2O}}{760} \cdot \frac{273}{273 - T}$$

4. Neither H_2O nor CO_2 removed from sampled gas, no interference with analyzers, heated sample tubing to prevent condensation:

$$V_{A_{BTPS}} = (V_{I_{ATPD}} - V_{D_{INST}} - V_{D_{ANAT}}) \cdot \frac{F_{I_{Tr}}}{F_{S_{Tr}}} \cdot \frac{310}{273 - T}$$

$$V_{A_{STPD}} = (V_{I_{ATPD}} - V_{D_{INST}} - V_{D_{ANAT}}) \cdot \frac{F_{I_{Tr}}}{F_{S_{Tr}}} \cdot \frac{P_B - 47}{760} \cdot \frac{273}{273 - T}$$

In these calculations, room temperature (T) is measured in Celsius and gas pressures are measured in mm Hg. P_B is barometric pressure; P_{H_2O} is ambient water vapor pressure in these equations. $V_{D_{INST}}$ = instrument dead space, $V_{D_{ANAT}}$ = anatomic dead space. $F_{I_{Tr}}$ is the fraction of tracer gas in the inspired test gas. F_{ACO_2} is the fraction of CO_2 in the alveolar sample. $F_{S_{Tr}}$ refers to the measurement of the tracer gas (Tr) in the alveolar sample and may differ from $F_{A_{Tr}}$, depending on the effects of CO_2 and H_2O as noted. In all four cases, V_I is the measured volume of inhaled dry gas and is thus considered under ATPD conditions. The conversion to BTPS and STPD may require factors to compensate for the diluting or concentrating effects of adding or deleting H_2O or CO_2 at the gas sampling site. Standard gas condition conversion formulas must therefore be adjusted as described above.

Recommendations. Depending on how CO_2 and H_2O affect the gas analyzers and the system used to compensate for these gases, different calculations of V_A may be required as outlined in Table 4. Manufacturers must determine and document the appropriate corrections for their systems.

Gas conditions of V_A in D_L/V_A. In the expression D_L/V_A, V_A is variably reported at BTPS (31) or STPD (96, 97) conditions. Most recommendations now suggest that it be expressed at BTPS conditions (3, 4). Recent normal values also uniformly report the D_L/V_A in ml CO (STPD)/min/mm Hg/L (BTPS) (98–101). When V_A is expressed at STPD, D_L/V_A varies with altitude. D_L/V_A is independent of altitude when V_A is expressed at BTPS.

Recommendation. V_A in the denominator of D_L/V_A should be reported at BTPS conditions. The traditional units of D_L/V_A are, therefore, ml CO (STPD)/min/mm Hg/L (BTPS). This recommendation is based on the clinical experience of the conference members and on the independence of D_L/V_A from altitude when V_A conditions are BTPS.

Interpreting the Results

Acceptability, reproducibility, and number of tests. Acceptable tests are defined in Table 5. Reproducibility describes the variation in multiple tests. The common statement that duplicate measurements of D_{LCO} measured within a single testing session (intrasession) should be within 5 to 6% of each other is based on a coefficient of variation (CV) of repeated measurements in normal subjects of 5 to 6%. Intrasession CVs of 3 to 4% can be achieved (30, 102). In contrast, intercession D_{LCO} variability of up to 9% has been documented in normal individuals in repeated measurements over a period of 1 yr (103). Because most intrasession variability is technical rather than physiologic, the mean of acceptable tests is reasonable to report.

Intrasession CV for repeated measures of D_{LCO} increases with increasing airway obstruction (104–106). Therefore, expected reproducibility should be worse in patients with airway obstruction when percent difference between duplicate measurements is used as the only criterion. The exact method by which mea-

TABLE 5

ACCEPTABLE TEST CRITERIA FOR D_{LCO}

1.	Use of proper quality controlled equipment.
2.	Inspired volume of > 90% VC in less than 4 s.
3.	A stable breath-hold for 9–11 s. There should be no evidence of leaks or Valsalva or Muller maneuvers.
4.	Expiration in less than 4 s with appropriate clearance of dead space and proper sampling/analysis of alveolar gas.

sured CV can be translated into a standard is not clear. It is clear that using ± 1 CV is not statistically justifiable. A more acceptable standard would be ± 2 CV or ± 10%. In patients with a reduced D_{LCO}, even 10% may be too restrictive. Until more information is available, there is no reason to change the 1987 standards (6).

Current standards recommend at least two D_{LCO} tests be performed (6), but research is needed to determine the actual number of tests required to provide a reasonable estimate of average D_{LCO} value for a given person.

Recommendation. There should be at least two acceptable tests that meet the reproducibility requirement of being within ± 10% or 3 ml CO (STPD)/min/mm Hg of the average D_{LCO}. The average of at least two acceptable tests that meet this reproducibility requirement should be reported.

Adjustment for hemoglobin concentration. That D_{LCO} changes as a function of hemoglobin concentration (Hb) is well known. All current methods of adjusting for Hb involve unproved assumptions, and no method has been uniformly accepted. Different methods of adjustment produce widely divergent adjustment factors when changes in Hb are large.

The most commonly used method of adjusting D_{LCO} for Hb is that of Cotes and associates (45, 107). They offered a theoretical approach in which D_{LCO} is adjusted to a standard Hb of 14.6 g/dl using the relationship described by Roughton and Forster (11), where $1/D_L = 1/D_M + 1/\theta V_c$ and θ is assumed to be proportional to the standard hemoglobin and $D_M/\theta V_c$ is assumed to be 0.7. The previous D_{LCO} standards document (6) recommended adjustment of D_{LCO} to a standard hemoglobin of 14.6 g/dl for everyone. On average, this recommendation resulted in a relatively small adjustment factor for adult men whose average Hb is not far from 14.6 g/dl. In contrast, for adult women and children under age 15 whose average Hb is about 13.4 g/dl, the average correction factor was much larger, potentially introducing more error into the adjustment. In this document separate adjustments for these two groups are recommended to minimize the size of the average correction factor applied to measured D_{LCO}. The choice of 13.4 g/dl as a standard Hb for women is slightly different than the normalization to a Hb of 12.8 recommended in the ATS guidelines for evaluation of disability (108).

The equation for adjustment to an Hb of 14.6 g/dl (appropriate for adolescent and adult men) is:

$$\text{Hb-adjusted } D_{LCO} = \text{observed } D_{LCO}\ (10.22 + \text{Hb})/1.7\ \text{Hb}$$

The equation for adjustment to an Hb of 13.4 g/dl (appropriate for children under 15 yr of age and women) is:

$$\text{Hb-adjusted } D_{LCO} = \text{observed } D_{LCO}\ (9.38 + \text{Hb})/1.7\ \text{Hb}$$

Investigators have offered other equations for the correction for Hb, many of which are similar to the correction factor described by Cotes and colleagues (45, 107). Others have suggested incorporation of Hb or hematocrit into reference equations (99, 109).

The ITS (3) and the ERS (7) recommend the equation described by Cotes and coworkers (45, 107). Adjusting either the measured or predicted D_{LCO} will allow interpretative statements to be made about whether the differences between measured and predicted can be explained by differences in hemoglobin concentration.

Recommendation. The equation described by Cotes and colleagues (45, 107) should serve as the basis for hemoglobin adjustments. An adjustment of D_{LCO} for Hb is desirable as part of the interpretation. It is especially important to measure Hb or hematocrit in situations where Hb would be expected to vary from the norm (e.g., hemorrhage, malignancy, or exposure to cytotoxic medications). If an adjustment factor is used, measured D_{LCO} should be adjusted to an Hb of 14.6 g/dl for males over 15 yr of age and to 13.4 g/dl for women and children of either gender under age 15. Both the unadjusted and adjusted values should be reported. If the predicted rather than the measured D_{LCO} is adjusted, both the adjusted and unadjusted predicted values should be reported. If reference equations that incorporate Hb or hematocrit are used, the measured Hb or hematocrit should be reported.

Adjustment for carboxyhemoglobin concentration and CO back pressure. The routine D_{LCO} computation assumes that carbon monoxide back pressure (i.e., CO partial pressure in the blood) is zero. However, cigarette smoke as well as other environmental sources can produce measurable levels of CO back pressure and carboxyhemoglobin (COHb). Exposure to ordinary environmental CO and endogenous production of CO as a byproduct of hemoglobin catabolism commonly result in measured COHb levels of 1 to 2% (110). Small increases in COHb occur when CO is inspired in the D_{LCO} test. Frey and associates, for example, found that COHb increased about 0.7% with each single-breath D_{LCO} test (75). Ogilvie and associates (46) estimated that a COHb level of 10% would result in an 8% underestimation of D_{LCO} but recommended no adjustment because it was difficult to measure COHb at that time. Instead, they suggested subjects minimize the COHb level by not smoking on the day of the test. Cadigan and coworkers (111), Frans and associates (112), and Mohsenifar and Tashkin (113) have shown that the effect of COHb in reducing D_{LCO} is greater than would be predicted by the back pressure effect alone. Frans and associates (112) suggest that as COHb increases, the effective hemoglobin mass decreases, thereby decreasing D_{LCO} in what they call an "anemia" effect. They reported that D_{LCO} decreased about 1.2% for each percent increase in COHb; about 60% of the decrease is due to the effect of back pressure and 40% is due to the "anemia" effect. Mohsenifar and Tashkin (113) showed that D_{LCO} is decreased about 1% for each 1% increase in COHb. Estimates from the data of Cadigan and coworkers (111) suggest the effect of COHb is also about a 1% decrease in D_{LCO} for each 1% increase in COHb.

Carboxyhemoglobin concentrations can now be easily measured using CO oximeters, and CO back pressure can be measured in expired gas. Alternatively, simple methods of estimating CO content in blood have been published (114–116). Adjusting for CO back pressure is now easier and reasonable. Remember, however, that adjustment for only back pressure will not fully adjust D_{LCO} for the total effect of COHb. Leech and colleagues (86) emphasized the importance of adjusting D_{LCO} for the effect of COHb, especially in an epidemiologic setting where small changes in D_{LCO} between groups of people are important.

The 1–2% baseline COHb levels attributable to endogenous production of CO and ordinary environmental exposures are already incorporated into reference values based on healthy nonsmoking subjects.

Recommendations. An adjustment for COHb is not required but is recommended for interpretative purposes when COHb is elevated. Measured D_{LCO} can be adjusted for COHb and CO back pressure in one of two ways:

TABLE 6

D_{LCO} REFERENCE EQUATIONS FOR ADULTS

Reference No.	N	Equation	r2	SEE	Smoking Status
Men					
96	84	6.8 − 0.238A − 15.5BSA	*	5.04	*
45	227	0.325H − 0.200A − 17.6	*	5.10	*
102	*	3.75VA − 0.153A + 19.93	*	*	*
98†	123	0.410H − 0.210A − 26.31	0.60	4.82	NS
83	74	0.1646H − 0.229A − 12.9113	0.46	4.84	NS
101	80	0.441H − 0.1936A − 31.3822	0.32	5.79	NS
99	71	0.3551H − 0.2741A − 11.3527	0.67	4.57	NS
4	‡	0.3319H − 0.1971A − 18.006	0.79	4.21	*
119	194	0.3674H − 0.1961A − 21.8982	0.45	4.40	NS
Women					
96	51	0.5 − 0.117A + 15.5BSA	*	5.04	*
120	41	0.212H − 0.156A − 2.66	*	3.69	*
102	*	5.38VA − 0.083A + 7.72	*	*	*
98§	122	0.256H − 0.144A − 8.36	0.56	3.57	NS
83	159	0.1602H − 0.1111A − 2.2382	0.54	3.95	NS + ES
101	291	0.1569H − 0.0677A + 5.0767	0.09	4.31	NS
99	99	0.1872H − 0.1460A + 3.8821	0.38	4.50	NS
4	‡	0.2441H − 0.1463A − 8.20	0.44	3.49	*
119	167	0.1369H − 0.1233A − 0.0917W + 1.8879	0.37	2.91	NS

Definition of abbreviations: VA = alveolar volume in L STPD; H = height in cm; A = age in years; W = weight in kg; BSA = body surface area; ECCS = European Community for Coal and Steel; NS = nonsmokers; ES = ex-smokers; r2 = coefficient of determination; SEE = standard error of the estimate. Estimates of regression variability are listed under SEE regardless of how the author labeled the variability.

Modified with permission from reference 17.

* Information not available in reference.

† Adjusted to a standard hemoglobin concentration of 14.6 g/dL.

‡ Summary equations from several studies.

§ No adjustment for hemoglobin (Hb) concentration; average Hb for the study population was 13.3 g/dl.

1. Measure COHb directly or estimate the COHb. The following equation empirically corrects for both CO back pressure and the "anemia" effect of COHb on D_{LCO} (113):

$$\text{COHb-adjusted } D_{LCO} = \text{measured } D_{LCO}\,(1 + [\%\ \text{COHb}/100])$$

2. CO back pressure can be measured in expired gas before a D_{LCO} maneuver or estimated using one of several available techniques (113–116). D_{LCO} can then be recalculated after subtracting the estimated CO back pressure from both $F_{ACO,0}$ and $F_{ACO,t}$. Units must be consistent before making the subtraction (i.e., back pressure must be estimated in the same units [% or mm Hg] as the measured CO levels in the calculation of D_{LCO}). This method will not adjust D_{LCO} for the "anemia" effect of COHb and is less preferable than method 1.

Observed and predicted D_{LCO} values should always be reported. If an adjustment is made for CO back pressure, the method of adjustment should be specified and the adjusted measured or predicted value reported consistent with the adjustment for hemoglobin.

Adjustments for altitude-induced changes. Given a constant F_{IO_2}, increasing altitude will result in a decrease in P_{IO_2} and increase D_{LCO} about 0.35% per mm Hg decrease in alveolar sample P_{O_2} (P_{AO_2}) (71) or about 0.31% per mm Hg decrease in P_{IO_2} (72). Adjustments to a standard P_{AO_2} of 120 mm Hg may be made using a measured P_{AO_2} as follows:

$$\text{Altitude-adjusted } D_{LCO} = \text{measured } D_{LCO} \times (1.0 + 0.0035[P_{AO_2} - 120])$$

Alternatively, an average adjustment for interpretative purposes only can be made for a given altitude as follows, assuming an average P_{IO_2} of 150 mm Hg at sea level (72):

$$\text{Altitude-adjusted } D_{LCO} = \text{measured } D_{LCO} \times (1.0 + 0.0031[P_{IO_2} - 150])$$
$$(\text{estimated } P_{IO_2} = 0.21\ [P_B - 47])$$

Adjustments based on average altitudes may be more variable than adjustments based on individual measurements of P_{AO_2}. Altitude effects on increasing Hb concentration will also affect the measurement of D_{LCO} (see above). It is not known whether increasing altitude has other effects on D_{LCO}.

Recommendations. The uncorrected D_{LCO} should always be reported. Adjustment for altitude is permitted but not required. The choice of adjusting the measured or the predicted value and the method of reporting should be consistent with the adjustments of other factors in the measurement and reporting of D_{LCO}.

Reference equations. Selecting reference equations for D_{LCO} remains a problem. Large differences have been observed among different reference equations and among different laboratories (Table 6). Currently, most reference equations use height, sex, and age to predict D_{LCO}. Alternative equations are available that use alveolar volume (VA) in the prediction equation (102). The use of VA in a prediction equation provides a form of normalization for lung volume exposed to the test gas.

Until more information is available, it is important for every laboratory to ensure that normal D_{LCO} and D_L/V_A values measured in their laboratory match the predicted values they use. Physicians should be alert to the possibility that reference values in the laboratory they use may be inappropriate for their patient clientele. Predicted values consistently inappropriate for the clinical situation should lead to a re-examination of both the test technique and the reference equations. Formal comparison of measured and predicted values will identify the most appropriate reference equations (117). The committee recommends that a number of healthy individuals (asymptomatic, nonobese, nonsmokers with a normal physical examination of the chest and abdomen and normal hemoglobin concentrations) be tested. The measured and predicted values should be compared by calculating residuals (measured minus the predicted) for each subject. The reference equation producing the sum of residuals closest to zero will probably provide the best fit, although there is no current research to suggest what index of best fit is most appropriate. The number of subjects needed to provide an accurate estimate of fit is also unknown. Preliminary work (117) suggests that five is not enough and that 15 to 20 may be a reasonable compromise between accuracy and effort. We suggest that at least 15 healthy subjects of each sex be tested and compared with reference equations to establish which equation will be most appropriate for a given laboratory. The subjects should be of varying heights and ages to define an adequate range. Further research is needed to guide the proper selection of reference equations.

Few good ethnic comparisons are available for D_{LCO} and therefore, little is known about its ethnic variation. One abstract reports a lower value in blacks (118). As this information becomes available, it will be important to include it in the selection of reference equations.

Recommendations. Each laboratory should select reference equations appropriate for the methods used and the population tested. Reference equations demonstrated to be appropriate for a given laboratory are especially important in the interpretation of lung function tests used to evaluate impairment or disability (25).

Interpretation when test specifications are not met. The specifications for test performance are fairly rigidly set and not all patients will be able to meet them. When standards are too rigid, valid data may be excluded if tests are rejected outright (for example, if the inspired volume is 85% of the largest vital capacity and the patient cannot meet the 90% requirement with three or four tries).

Recommendation. Such data should be reported with the caveat that the data are suboptimal. The interpretation should identify the discrepancy as well as the direction and magnitude of the potential error involved. Such errors may or may not be important in clinical decision making.

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American Thoracic Society
MEDICAL SECTION OF THE AMERICAN LUNG ASSOCIATION

Standardization of Spirometry
1994 Update

THIS OFFICIAL STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS ADOPTED BY THE ATS BOARD OF DIRECTORS, NOVEMBER 11, 1994

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The first American Thoracic Society (ATS) Statement on the Standardization of Spirometry was published 15 yr ago and was based on the Snowbird Workshop held in 1979 (1). This initial statement was updated in March 1987 (2) after 8 yr of practical experience with the initial recommendations. The state of the art of spirometry has continued to advance as a result of scientific studies that have provided additional data relating to performance of spirometry. The use of computers for spirometry measurement has become even more commonplace. New statements by the ATS (3) and the European Respiratory Society (4) also underscore the need to update the ATS statement on spirometry. This revision of the standards for spirometry reflects the changes in clinical emphasis and in available technology since the 1987 ATS spirometry update (2) was published. The changes in clinical emphasis and equipment include:

- The strong emphasis on the use of portable peak flow meters to monitor lung function in asthmatics by the National Heart, Lung, and Blood Institute's Asthma Education Program (5), the International Asthma Management Project (6), the British Thoracic Society (7), and others.
- The corresponding development of many new model peak flow monitoring devices, some purely mechanical and some electronic.
- A better understanding of the complexities of correcting spirometric values to BTPS conditions.

This statement was prepared by the Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. *Members of the committee*: Robert O. Crapo, M.D., Chairman, John L. Hankinson, Ph.D., Charles Irvin, Ph.D., Neil R. MacIntyre, M.D., Karen Z. Voter, M.D., and Robert A. Wise, M.D. *Spirometry Subcommittee*: John L. Hankinson, Ph.D., Subcommittee Chairman, Charles Irvin, Ph.D., Robert A. Wise, M.D. *Invited Spirometry and DLCO Workshop participants*: Brian Graham, Ph.D., Carl O'Donnell, Sc.D., Paolo Paoletti, M.D., Josep Roca, M.D., and Giovanni Viegi, M.D. *Corresponding members*: Margaret R. Becklake, M.D., A. Sonia Buist, M.D., Gary duMoulin, Ph.D., Robert L. Jensen, Ph.D., Albert Miller, M.D., and Andrea Rossi, M.D.

- A greater appreciation of the importance of the technicians and procedures in achieving good spirometric results.
- An increased concern about the risk of transmission of infectious diseases during pulmonary function testing.

We have responded to these changes by:

- Separating the standards for laboratory or diagnostic spirometers from those of devices designed to be used primarily as monitors.
- Adding BTPS testing to the testing of spirometers.
- Adding a section on performance of slow vital capacity.
- Strengthening and updating the procedural aspects of quality control, including an appendix with sample spirograms.
- Adding a section on hygiene and infection control.

A central goal of any guideline or standardization document is to improve performance and thus decrease the variability of laboratory testing. In 1979 (1), and again in 1987 (2), the perception was that the major source of variability was instrumentation. More recently, instrumentation has improved to a point where other sources of variability can be identified, in particular, procedural problems. In 1991, the ATS Statement on Lung Function Testing: Selection of Reference Values and Interpretation Strategies (3) stated: "The largest single source of within-subject variability is improper performance of the test." More recently, Enright and coworkers (8) have shown a positive impact of an extensive quality control program on spirometric results. As a consequence, there is an effort in the present statement to address issues of test performance and quality control.

The ATS statements on standardization of spirometry have had far-reaching effects on manufacturers and users of spirometers. In some cases, manufacturers have used the document as a minimum performance requirement document. We continue to be concerned with this approach and encourage manufacturers to seek excellence in design so that the state of the art for spirometers will *exceed* ATS recommendations. Some research protocols will necessitate even more stringent requirements than stated here.

Spirometry is a medical test that measures the volume of air an individual inhales or exhales as a function of time. Flow, or the rate at which the volume is changing as a function of time, may also be measured with spirometry. Spirometry, like the measurement of blood pressure, is a useful screen of general health. Like the simple measurement of blood pressure, it does not suffice in certain situations where more extensive testing is warranted. Spirometric results correlate well with morbidity and life expectancy. Spirometry is used to affect decisions about individual patients, including the nature of the defect, its severity, and the response to therapy. Table 1 lists some of the potential indications for spirometry.

Results from tests based on spirometric maneuvers can have an important effect on a person's lifestyle, standard of living, and future treatment (10). Similarly, accurate and precise spirometers are required for epidemiologic studies. Rates of improvement or deterioration of pulmonary function measured in relation to environmental exposures and/or personal characteristics may be erroneous if inaccurate spirometers are used or less sensitive if imprecise spirometers are used (11).

Maximizing the clinical usefulness of spirometry depends on a number of steps, ranging from equipment selection to interpretation, and ultimately involves clinical assessment. Figure 1 is a flow diagram of these steps.

The first step is establishing equipment performance criteria. The Snowbird Workshop (1), 1987 Update (2), and this update give recommendations for equipment used for spirometry.

The second step in the process involves validation that the spirometer design meets the minimum recommendations through the testing of a representative device. Detailed methods for performing the validation testing are outlined later in this statement. The ATS makes equipment recommendations but does not act as a certifying agency to verify compliance with these standards. Spirometer users should carefully select equipment that meets the ATS recommendations to assure that spirometry testing can be done accurately. Before purchasing a spirometer, it is wise to: (*1*) ask the manufacturer to provide summary data that demonstrates that the device being considered meets or exceeds ATS recommendations, or (*2*) review results of spirometry testing from independent testing laboratories. This statement does not mandate testing by an independent laboratory. There are many calibrated computer-driven syringes available. When an independent laboratory is not used, manufacturers should make the testing protocol, the raw data, and the summary data available to potential customers for their review.

Even after spirometers have been found to meet ATS recommendations, they (like other mechanical, electrical, or computer equipment) must be routinely checked for performance quality.

TABLE 1

INDICATIONS FOR SPIROMETRY*

Diagnostic
To evaluate symptoms, signs, or abnormal laboratory tests
—Symptoms: dyspnea, wheezing, orthopnea, cough, phlegm production, chest pain
—Signs: diminished breath sounds, overinflation, expiratory slowing, cyanosis, chest deformity, unexplained crackles
—Abnormal laboratory tests: hypoxemia, hypercapnia, polycythemia, abnormal chest radiographs
To measure the effect of disease on pulmonary function
To screen individuals at risk of having pulmonary diseases
—Smokers
—Individuals in occupations with exposures to injurious substances
—Some routine physical examinations
To assess preoperative risk
To assess prognosis (lung transplant, etc.)
To assess health status before enrollment in strenuous physical activity programs
Monitoring
To assess therapeutic interventions
—Bronchodilator therapy
—Steroid treatment for asthma, interstitial lung disease, etc.
—Management of congestive heart failure
—Other (antibiotics in cystic fibrosis, etc.)
To describe the course of diseases affecting lung function
—Pulmonary diseases
Obstructive airways diseases
Interstitial lung diseases
—Cardiac diseases
Congestive heart failure
—Neuromuscular diseases
Guillain-Barré Syndrome
To monitor persons in occupations with exposure to injurious agents
To monitor for adverse reactions to drugs with known pulmonary toxicity
Disability/Impairment Evaluations
To assess patients as part of a rehabilitation program
—Medical
—Industrial
—Vocational
To assess risks as part of an insurance evaluation
To assess individuals for legal reasons
—Social Security or other government compensation programs
—Personal injury lawsuits
—Others
Public Health
Epidemiologic surveys
—Comparison of health status of populations living in different environments
—Validation of subjective complaints in occupational/environmental settings
Derivation of reference equations

* Adapted from reference 9.

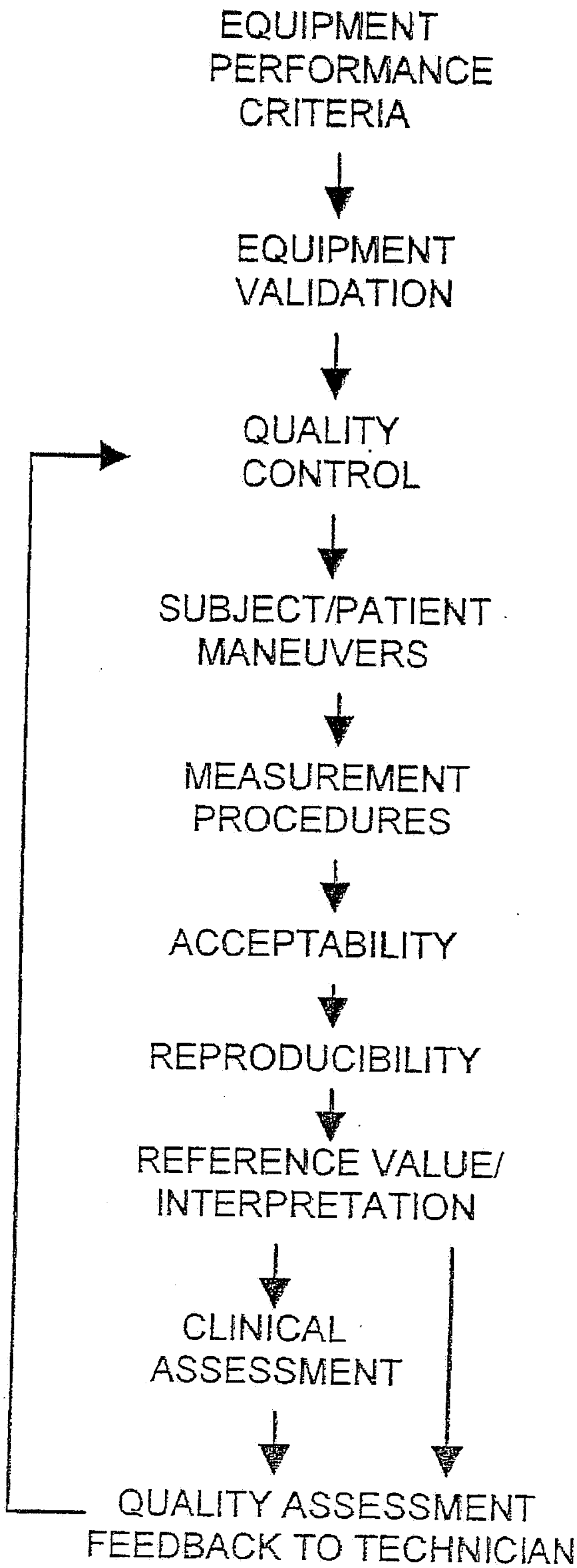


Figure 1. Spirometry standardization steps.

Recommendations for spirometer quality control have been developed by the ATS and are summarized in this statement.

Spirometry is an effort-dependent maneuver that requires understanding, coordination, and cooperation by the patient-subject, who must be carefully instructed. Thus, procedural recommendations are important components of testing. Part of the recommendation is to obtain a sufficient number of maneuvers of adequate quality and then determine if these acceptable maneuvers are reproducible, implying that maximal effort has been achieved. Once spirometry maneuvers have been performed, data are either measured by hand or computer. Measurement procedures are included in this article to help assure that uniform methods are used and comparable results are obtained. These recommendations include considerations such as using "back extrapolation" for determining the "start-of-test" time (zero point) for measures such as FEV_1 and the criteria to determine the end of the expiratory maneuver. Instruments that provide feedback to the technician in the form of checks on the adequacy of the data are clearly desirable.

The interactions between technicians and subjects are crucial to obtaining adequate spirometry, since it is such an effort-dependent maneuver. Technicians must be trained and must maintain a high level of proficiency to assure optimal results.

The spirogram tracing must be carefully scrutinized for quality. Recommendations about quality, acceptability, and reproducibility of test results are presented, as well as examples of unacceptable maneuvers (*see* APPENDIX A). After adequate results are obtained, they are usually compared with reference values to make an assessment (interpretation) of the results. The ATS 1991 Statement on Lung Function Testing: Selection of Reference Values and Interpretative Strategies provides guidelines for selecting reference values and interpreting the results. Clinical assessment should be an integral part of spirometry. Results obtained from spirometry are only one part of the much more complex patient-care relationship or research study analysis. It is the responsibility of the laboratory director to provide adequate quality control procedures to assure that an attempt to meet these recommendations and criteria has been made.

In both the original ATS statement on spirometry and the 1987 update, a rationale was provided for each recommendation. Since many of these recommendations and their rationales have not changed since the original statements, the reader is referred to the 1987 update (2) for the rationales concerning less controversial recommendations.

DEFINITIONS

All terms and abbreviations used here are based on a report of the American College of Chest Physicians (ACCP)–ATS Joint Committee on Pulmonary Nomenclature (12).

Accuracy and precision are important terms in equipment recommendations and warrant some definition. Accuracy error is the systematic difference between the "true" and the measured value. The accuracy of a spirometer system depends on a number of factors, including linearity and frequency response of the system or processor, sensitivity to environmental conditions, calibration, and adequacy of correction factors. Its precision depends on the signal/noise ratio and on the resolution (i.e., the minimal detectable volume or flow). Precision error, usually denoted reproducibility, is the numerical difference between successive measurements (4). For example, if a volume spirometer's pen is not on zero but at 1 L, all volumes read directly from the graph would be overread by 1 L. The accuracy error would be 1 L, since the measured volume would read 3 L when the true volume is 2 L. However, the precision of the spirometer would remain unchanged, as the spirometer would consistently read 3 L each time 2 L is injected into the spirometer. For some applications, e.g., peak expiratory flow (PEF) monitoring, precision is more important than accuracy.

In several sections of this document, the terms "open circuit" and "closed circuit" technique are used. The term "open circuit" spirometry refers to the method of conducting spirometry where the subject takes a full inspiration before inserting the mouthpiece to perform the test. In this approach, the subject does not inhale from the spirometer or potentially contaminated flow sensor. The term "closed circuit" spirometry refers to the method of conducting spirometry where the subject is attached to the mouthpiece before the inspiration is begun, and often several tidal breaths are obtained. In this approach, the subject does inhale from the spirometer. There are advantages and disadvantages to both of these approaches and both are recommended procedures. For example, an advantage of the closed circuit technique is that it allows measurement of expiratory reserve volume (ERV), tidal volume (TV), and inspiratory flows.

Previous recommendations (1, 2) treated all spirometers alike whether used for clinical, diagnostic, or epidemiologic purposes. However, a new class of device has been added for monitoring purposes. Monitoring devices (portable peak flow meters, etc.) have separate recommendations from diagnostic spirometers for the recorder/display requirements as well as the accuracy requirements. In addition, precision requirements have been added for monitoring devices. Recommendations concerning monitoring devices are identified in this statement by the notation, "Monitoring." We do *not* recommend the use of monitoring devices for diagnostic purposes in the traditional diagnostic setting where one is comparing a measured value with a reference value. In this setting, monitoring instruments are likely to be inadequate because: (*1*) they may be less accurate than diagnostic instruments; (*2*) they usually cannot be calibrated or checked to assure their performance; (*3*) their graphical displays may be missing or inadequate to allow proper evaluation of the subject's effort and overall test quality; and (*4*) current PEF standards of ± 10% allow models of instruments to vary by up to 20%, adding variability to reference values derived when a monitoring instrument is used. However, monitoring instruments may be useful in diagnosing excessive variability in spirometric parameters because they tend to have excellent precision.

EQUIPMENT RECOMMENDATIONS

Accurate results require accurate equipment. Spirometer equipment recommendations apply to all diagnostic spirometers whether used for clinical or epidemiologic purposes. Instrumentation recommendations should be followed to provide accurate spirometric data and information that are comparable from laboratory to laboratory and from one time period to another (1). The accuracy of a spirometry system depends on the resolution (i.e., the minimal detectable volume or flow) and linearity of the entire system, from volume or flow transducer to recorder, display, or processor. Errors at any step in the process can affect the accuracy of the results. For example, if the BTPS correction factor is in error, an accurate, uncorrected FVC will be corrupted when the factor is applied.

Recommendations are first provided for diagnostic spirometers, followed by recommendations for monitoring devices under the subheading, "Monitoring." For example, the equipment recommendations for diagnostic spirometry are summarized in Table 2 and for monitoring devices in Table 3. Spirometers are not required to measure all the following parameters but must meet the recommendations for those parameters that are measured. Accuracy and precision recommendations apply over the entire volume range of the instrument.

TABLE 2

MINIMAL RECOMMENDATIONS FOR DIAGNOSTIC SPIROMETRY*

Test	Range/Accuracy (BTPS)	Flow Range (L/s)	Time (s)	Resistance and Back Pressure	Test Signal
VC	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	30		3-L Cal Syringe
FVC	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	15	Less than 1.5 cm H_2O/L/s	24 standard waveforms 3-L Cal Syringe
FEV_1	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	1	Less than 1.5 cm H_2O/L/s	24 standard waveforms
Time zero	The time point from which all FEV_t measurements are taken			Back extrapolation	
PEF	Accuracy: ± 10% of reading or ± 0.400 L/s, whichever is greater Precision: ± 5% of reading or ± 0.200 L/s, whichever is greater	zero to 14		Same as FEV_1	26 flow standard waveforms
$FEF_{25-75\%}$	7.0 L/s ± 5% of reading or ± 0.200 L/s, whichever is greater	± 14	15	Same as FEV_1	24 standard waveforms
$\dot{V}$	± 14 L/s ± 5% of reading or ± 0.200 L/s, whichever is greater	zero to 14	15	Same as FEV_1	Proof from manufacturer
MVV	250 L/min at TV of 2 L within ± 10% of reading or ± 15 L/min, whichever is greater	± 14 ± 3%	12 to 15	Pressure less than ± 10 cm H_2O at 2-L TV at 2.0 Hz	Sine wave pump

* Unless specifically stated, precision requirements are the same as the accuracy requirements.

Recommendation: Vital Capacity (VC)

VC = The maximal volume of air exhaled from the point of maximal inhalation or the maximal volume of air inhaled from a point of maximal exhalation can be measured with a slow exhalation or inhalation, respectively. This was previously called the "slow" vital capacity and has been better described as the "relaxed vital capacity" (13). The VC is expressed in liters (BTPS). BTPS is body conditions: normal body temperature (37° C), ambient pressure, saturated with water vapor. When the rebreathing technique is used, an oxygen supply may be provided and carbon dioxide absorbed to account for oxygen consumption and the production of carbon dioxide. In this case, the oxygen supply must account for the total oxygen consumed, maintaining the volume constant at functional residual capacity. If this is not done properly, an incorrect VC could be obtained. Because of this potential error, the rebreathing technique with the absorption of carbon dioxide is discouraged as a technique when only VC is to be measured.

Rationale. In some subjects, a slow or relaxed vital capacity provides a more accurate determination of the vital capacity than those obtained with a forced exhalation. Forced expiratory volumes are usually lower than those obtained with a slow exhalation in subjects with airways obstruction and in older subjects. With severe airways obstruction, VC values may be larger than FVC values by as much as 1 L.

TABLE 3

MINIMAL RECOMMENDATIONS FOR MONITORING DEVICES

Requirement	FVC & FEV_1 (BTPS)	PEF (BTPS)
Range	High: 0.50 to 8 L Low: 0.5 to 6 L	High: 100 L/min to ≥ 700 L/min but ≤ 850 L/min Low: 60 L/min to ≥ 275 L/min but ≤ 400 L/min
Accuracy	± 5% of reading or ± 0.100 L, whichever is greater	± 10% of reading or ± 20 L/min, whichever is greater
Precision	± 3% of reading or ± 0.050 L, whichever is greater	Intradevice: ≤ 5% of reading or ≤ 10 L/min, whichever is greater Interdevice: ≤ 10% of reading or ≤ 20 L/min, whichever is greater
Linearity	Within 3% over range	Within 5% over range
Graduations	Constant over entire range High: 0.100 L Low: 0.050 L	Constant over entire range High: 20 L/min Low: 10 L/min
Resolution	High: 0.050 L Low: 0.025 L	High: 10 L/min Low: 5 L/min
Resistance	Less than 2.5 cm H_2O/L/s, from zero to 14 L/s	Less than 2.5 cm H_2O/L/s, from zero to 14 L/s
Minimal detectable volume	0.030 L	—
Test Signal	24 standard volume-time waveforms	26 standard flow-time waveforms

High = high range and low = low range devices.

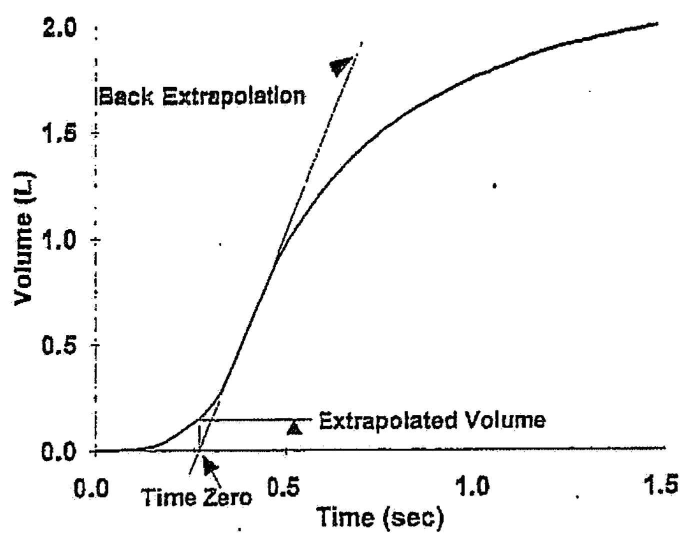


Figure 2. Typical subject waveform of a volume–time spirogram illustrating back extrapolation to determine "time zero." Extrapolated volume = Vext.

For measurements of VC, the spirometer must be capable of accumulating volume for *at least* 30 s. Spirometers must be capable of measuring volumes of *at least* 8 L (BTPS) with flows between zero and 14 L/s with a volume accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater.

Recommendation: Forced Vital Capacity (FVC)

FVC = Maximal volume of air exhaled with maximally forced effort from a position of maximal inspiration, i.e., vital capacity performed with a maximally forced expiratory effort, expressed in liters (BTPS).

The diagnostic spirometer must be capable of measuring volumes up to *at least* 8 L (BTPS) with an accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater, with flows between zero and 14 L/s. The 8-L range requirement applies to newly manufactured instruments; existing spirometers with a 7-L range may continue to be used. The spirometer must be capable of accumulating volume for *at least* 15 s, although longer times are recommended.

Monitoring. Monitoring devices must be capable of measuring volumes up to *at least* 8 L (BTPS) with an accuracy of *at least* ± 5% of reading or ± 0.100 L, whichever is greater, with flows between zero and 14 L/s. The precision of the monitoring devices must be *at least* ± 3% of reading or ± 0.050 L, whichever is greater. The device must be capable of accumulating volume for *at least* 15 s.

Recommendation: Timed Forced Expiratory Volume (FEV_t)

FEV_t = The volume of air exhaled in the specified time during the performance of the FVC, e.g., FEV_1 for the volume of air exhaled during the first second of FVC, expressed in liters (BTPS).

Measuring FEV_t requires a spirometer capable of measuring volumes of *at least* 8 L. The spirometer must measure FEV_t within an accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater, with flows between zero and 14 L/s. The start-of-test for purposes of timing *must be* determined by the back extrapolation method (1, 14, 15) or a method shown to be equivalent (Figure 2). For manual measurements, the back extrapolation method traces back from the steepest slope on the volume–time curve (Figure 2) (15, 16). For computer methods of back extrapolation, we recommend using the largest slope averaged over an 80-ms period (17). The total resistance to airflow at 14.0 L/s must be less than 1.5 cm H_2O/L/s. The total resistance must be measured including any tubing, valves, pre-filter, etc., that may be inserted between the subject and the spirometer. Since some devices may exhibit changes in resistance due to water vapor condensation, resistance requirements must be met under BTPS conditions when up to eight successive FVC maneuvers are performed in a 10-min period.

Monitoring. The monitoring device must be capable of measuring FEV_t up to *at least* 8 L (BTPS) with an accuracy of *at least* ± 5% of reading or ± 0.100 L, whichever is greater, with flows between zero and 14 L/s. The precision of the monitoring devices for FEV_t must be *at least* ± 3% of reading or ± 0.050 L, whichever is greater. Resistance should be less than 2.5 cm H_2O/L/s and the start-of-test requirement is the same as for diagnostic spirometry.

Recommendation: PEF

PEF = Largest expiratory flow achieved with a maximally forced effort from a position of maximal inspiration, expressed in liters/second (BTPS).

Measuring PEF requires an instrument that has a frequency response that is flat (± 5%) up to 12 Hz. The instrument must measure PEF within an accuracy of ± 10% of reading or ± 0.300 L/s, whichever is greater. Intra-instrument precision must be less than 5% of reading or 0.150 L/s, whichever is greater. Interdevice precision must be less than 10% or 0.300 L/s, whichever is greater.

The following or an equivalent method can be used in the determination of FEF_{max} or PEF for volume–time curves. However, the method used to derive PEF may depend on the measuring instrument (18), and the final determination of compliance should be determined through testing using the standard waveforms (26 flow–time waveforms, APPENDIX D), with PEF derived from the flow–time waveform (Table D1, column 2).

Determination of PEF can be performed from the volume–time data by using a parabolic curve-fitting algorithm, which smooths the data using a least squares parabolic fit to a 40- or 80-ms segment (np = 2 or 4) of the volume–time curve, or:

$$\text{flow}(n) = \frac{\sum_{j=-np}^{np} j\cdot \text{vol}(n+j)}{2\cdot h\cdot \sum_{j=1}^{np} j\cdot j} \qquad \text{PEF} = \text{Max (flow)}$$

where flow = an array of flow values from start to end of test; n = index of current flow data point (n = [np + 1] to index value of end of test); vol = an array of volume values; j = an index value as indicated in the equation; h = the time between samples (0.01 s in this example); np = the number of data points (for a 40-ms segment, np = 2 and for an 80-ms segment, np = 4); and PEF is the maximum value observed in the array flow.

Rationale. Using the 26 flow–time waveforms to define PEF is a change from the ATS 1987 Update. The PEFs for the 24 standard volume–time waveforms and the FEF_{max} described in the 1987 ATS Spirometry Update used the above algorithm with an 80-ms interval. Manufacturers, through the use of mechanical simulators and the 24 standard volume–time waveforms, have been implementing this or equivalent methods through their attempts to derive PEFs similar to those defined by the 24 standard volume–time waveforms.

In addition, the National Asthma Education Program (NAEP) (5) has adopted ATS standard volume–time waveform number 24 as their standard for portable PEF meters. Hankinson and Crapo (18) have shown that reducing the time interval in the above equation from 80 to 40 ms results in as much as an 8% higher PEF for two of the 24 standard volume–time waveforms and a

5% higher PEF value for waveform number 24. Regardless of this apparent change, PEF is a flow parameter and therefore should be defined based on a flow–time waveform rather than a volume–time waveform (i.e., waveform number 24). The final determination of compliance should be determined through testing using the standard 26 flow–time waveforms (APPENDIX D) and the PEF derived from the flow–time curve (Table D1, column 2). This approach allows all of an instrument's characteristics to be considered, rather than only the PEF computational algorithm. Because PEF is more variable than FVC and FEV_1 and because of the confusion surrounding PEF definition, a relatively large ± 10% accuracy requirement was allowed.

Recommendation (Monitoring): PEF

PEF = Largest expiratory flow achieved with a maximally forced effort from a position of maximal inspiration, expressed in liters/minute (BTPS).

Monitoring PEF also requires an instrument that has a frequency response that is flat (± 5%) up to 12 Hz and a resistance less than 2.5 cm H_2O/L/s with flows up to 14 L/s. The instrument must measure PEF within an accuracy of ± 10% of reading or ± 20 L/min, whichever is greater, with PEFs between 60 to 400 L/min for children and from 100 to 850 L/min for adults. The lower limit range of the instrument must be less than or equal to 60 L/min for children and 100 L/min for adults. The upper limit range must be greater than or equal to 275 L/min but less than 400/L min for children and greater than or equal to 700 L/min but less than 850 L/min for adults. If manual reading of the instrument is used, the reader must be able to resolve at least 5 L/min for low range (children) and 10 L/min for high range (adults) (marked PEF intervals [graduations] no greater than 10 L/min for low range and 20 L/min for high range). Intra-instrument precision must be less than or equal to 5% of reading or 10 L/min, whichever is greater. Interdevice precision must be less than 10% or 20 L/min, whichever is greater. Data on the instrument's life span and durability must be provided by the manufacturer, specified as the typical life span over which the instrument will satisfy the requirements of this section.

In addition to the above requirements, PEF measuring devices must also provide a method of reporting values at BTPS. For portable PEF meters, BTPS correction may be accomplished by limiting the environmental operational range for the instrument in terms of barometric pressure (altitude) and ambient temperature. Portable PEF meters must meet the accuracy and precision requirements above, given the range of environmental conditions encountered with typical use. A 10% accuracy requirement, higher than the 5% for other flows, is recommended to allow for potential BTPS correction complications associated with PEF measurements. Besides providing a method of correcting PEF values to BTPS, the instrument's manufacturer must also provide a correction for the effects of altitude or other environmental conditions as appropriate.

A package insert must be provided with each portable PEF meter containing *at least*: (*1*) clear instructions (with illustrations) for use of the instrument in simple terms that are understood by the general public; (*2*) instructions concerning maintenance of the instrument and methods to recognize when it is malfunctioning; and (*3*) appropriate actions to be taken when PEF readings change appreciably (i.e., whom to contact).

Rationale. Concerning the requirement of a flat frequency response up to 12 Hz, Lemen and coworkers (19) have shown that the mean highest frequency (HF) with significant amplitude content was 5.06 Hz in healthy individuals and 6.4 Hz in patients and smokers. They concluded that flow measuring devices should have a frequency response that is flat up to 12 Hz. Peslin and coworkers (20) found a slightly higher HF of about 10 Hz in healthy males and 7.5 Hz in female subjects. In addition, current mechanical waveform-generating equipment generally cannot accurately produce waveforms with frequency content above 12 Hz. The accuracy recommendation is less stringent for PEF than for the FVC and FEV_1 (10% versus 5%) because of the higher within- and between-subject variabilities associated with PEF measurements and because of testing instrument limitations. The PEF instrument precision and intra-instrument variability recommendations are lower (5%) than the accuracy and inter-instrument variability requirements (10%) because of the need for low instrument variability in the routine use of PEF meters for serial measurements. In addition, several studies have shown PEF meters to be much more precise than accurate (21–23). These recommendations are also similar to those of the NAEP (5). The range recommendations are made with the understanding that PEF measurements are often made using portable PEF meters. With these meters, reading resolution (number of graduations) must be balanced against the range of the meter (upper and lower meter limits). Therefore, different instrument ranges for children and adults are appropriate. The range recommendations for children are not intended to preclude the use of an instrument with adult ranges if the instrument meets the resolution requirements (ease of reading) for children.

An instrument's life span and durability are difficult to determine and will be specific to an instrument. However, portable peak flowmeters are often used for extended periods of time. Therefore, the instrument manufacturer must provide information on the typical life span of their instrument as well as cleaning and other maintenance instructions. The package insert requirements recommended by the NAEP (5) are similar to those recommended in this statement.

Recommendation: $FEF_{25-75\%}$

$FEF_{25-75\%}$ = Mean forced expiratory flow during the middle half of the FVC. Formerly called the maximal mid-expiratory flow (MMEF), expressed in liters/second (BTPS).

The $FEF_{25-75\%}$ must be measured with an accuracy of *at least* ± 5% of reading or ± 0.200 L/s, whichever is greater, over a range of up to 7 L/s. The $FEF_{25-75\%}$ must be measured on a system that meets diagnostic FVC recommendations.

Recommendation: Flow ($\dot{V}$)

$\dot{V}$ = Instantaneous forced expiratory flow (except for PEF), expressed in liters/second (BTPS).

Flow may be measured electronically or manually from a flow–volume display with adequate size for hand measuring. Where flow–volume loops or other uses of flow are made, with flow in the range of −14 to 14 L/s, the flow must be measurable to within ± 5% of reading or ± 0.200 L/s, whichever is greater.

Recommendation: Forced Expiratory Time (FET%)

FET% = Time from the back-extrapolated "time zero" until a specified percentage of a maneuver's FVC is exhaled, expressed in seconds. For example, FET95% would be the time required to reach 95% of a maneuver's FVC. See APPENDIX A for FET% examples. FET100% would be defined as the time required to reach the FVC or the time at which the volume was observed to be at its highest level. For maneuver quality assessment purposes, the reporting of the FET99% (24) or FET100% is encouraged but not mandated. Also, the FET25–75% (mid-expiratory time) may be a useful indicator of diminished flow when VC is decreased and may be less dependent on body or lung size than other flow parameters (25).

Recommendation: Forced Inspiratory Vital Capacity Maneuvers

These maneuvers are inspiratory vital capacity maneuvers performed with maximally forced effort from a position of maximal expiration to a position of maximal inspiration. Both volume and flow parameters are measured, which roughly correspond (except for direction) to those from the FVC maneuver. Volume measurements are expressed in liters (BTPS), flow measurements in liters/second (BTPS).

Rationale. Forced inspiratory maneuvers are useful in diagnosing and monitoring upper airway obstruction. They are usually performed either preceding or following the FVC maneuver but may be performed separately. Elderly or ill patients often have difficulty performing forced inspiratory and expiratory maneuvers as part of the same effort. Forced inspiratory maneuvers require the use of one of the closed circuit techniques.

For measurements of forced inspiratory spirometric parameters diagnostic spirometers must meet the corresponding range, accuracy, and precision recommendations specified for diagnostic spirometry systems (Table 2).

Recommendation: Maximal Voluntary Ventilation (MVV)

MVV = The volume of air exhaled in a specified period during repetitive maximal respiratory efforts, expressed in liters/minute (BTPS).

When a spirometer is used for measuring MVV, it must have an amplitude–frequency response that is flat within ± 10% from zero to 4 Hz at flow rates of up to 12 L/s over the volume range. The time for exhaled volume integration or recording must be no less than 12 s nor more than 15 s (26). The indicated time must be accurate to within ± 3%. The MVV must be measured with an accuracy of ± 10% of reading or ± 15 L/min, whichever is greater.

General Background: Spirometry Recorders/Displays

Paper records or graphic displays of spirometry signals are *required* and are used for:

1. Diagnostic function—when waveforms are to be used for quality control or review of the forced expiratory maneuver to determine if the maneuver was performed properly, so that unacceptable maneuvers can be eliminated.
2. Validation function—when waveforms are to be used to validate the spirometer system hardware and software for accuracy and reliability through the use of manual measurements (for example, measurement of FEV_1 using back extrapolation by comparing computer- and manually determined FEV_1).
3. Manual measurement function—when waveforms are to be manually measured for spirometric parameters (FVC, FEV_1, etc.) in the absence or failure of a computer.

With the continued advances in computer technology, there are many different ways to display and record spirometric waveforms. The committee continues to encourage use of computer technology.

Paper recorder requirements are the same regardless of the purpose, diagnostic, validation, or manual measurement. If no paper recorder or printer is available, then proof of validation of the accuracy and stability of the spirometer by an independent laboratory *must* be provided by the manufacturer. For these computer methods, any new software releases *must* also be validated.

Recommendation: Display of VC Maneuver

Either "open" or "closed" circuit technique may be used to measure the VC maneuver. Although the open circuit technique may be preferred because of hygiene concerns, this technique does not allow the monitoring (display) of the inhalation to TLC and therefore is less than optimum. Regardless of whether the open or closed circuit technique is used, a display of the entire VC maneuver must be provided. The maximal expiratory volume must be assessed to determine whether the subject has obtained a plateau in the expiratory effort. Subjects with airways obstruction usually exhibit different shaped curves at the end of their expiratory maneuver—a slope showing the nonhomogeneous emptying of lung units. Some patients with severe airways obstruction are not able to return to the level of FRC due to gas trapping (*see* APPENDIX A, VC maneuvers). In addition, important differences between inspiratory (IVC) and expiratory (EVC) maneuvers may be observed in patients with airways obstruction (27). For systems using a closed circuit with carbon dioxide absorption, a volume–time display is needed to verify baseline end-expiratory level (functional residual capacity or FRC). The graph should indicate the starting volume to evaluate the correct positioning of FRC.

Recommendation: Display of FVC Maneuver

Displays using flow versus volume instead of volume versus time expand the initial portions (first 1–2 s) of the forced vital capacity maneuver. Since this portion of the maneuver, particularly the peak expiratory flow, is correlated with the pleural pressure during the maneuver, the flow–volume display is useful to assess the magnitude of effort during the initial portions of the maneuver. Overlaying a series of flow–volume curves registered at apparent TLC (maximal inhalation, which may not be true TLC) is helpful in detecting a submaximal effort that may result in a large though nonreproducible FEV_1 as a consequence of negative effort dependence (28).

Unlike the flow–volume curve display, display of the FVC maneuver as a volume–time graph expands the terminal portions of the maneuver. Therefore, the volume–time display is useful in assessing the duration of effort and whether a plateau is achieved. Where spirometry may need to be reviewed by independent agencies, a volume–time tracing of sufficient size allows independent measurement and calculation of parameters from the FVC maneuvers. Overlaying a series of volume–time curves aligned at back-extrapolated time zero or flow–volume curves aligned at TLC is useful in evaluating reproducibility and submaximal efforts. For optimal quality control, both flow–volume and volume–time displays are useful and strongly encouraged. See APPENDIX A for illustrations of volume–time and flow–volume displays.

Recommendation: VC and FVC Maneuver Volume and Time Scales

Volume scale: When a volume–time curve is plotted or displayed, the volume scale must be *at least*: 10 mm/L (BTPS).

Time scale: *at least* 2 cm/s; larger time scales are preferred (at least 3 cm/s) when manual measurements are to be made (1, 29, 30). When the volume–time plot is used in conjunction with a flow–volume curve (both display methods are provided for interpretations and no hand-measurements are performed), the time scale requirement is reduced to 1 cm/s from the usually required minimum of 2 cm/s. This exception is allowed because, in these circumstances, the flow–volume curve can provide the means for quality assessment during the initial portion of the FVC maneuver. The volume–time curve can be used to evaluate the terminal portion of the FVC maneuver, and the time scale is less critical. For display of the slow VC, the volume scale may also be reduced to 1 cm/L and the time scale to 0.5 cm/s.

Recommendation: Flow–Volume Curves

When a flow–volume curve is plotted or displayed, exhaled flow must be plotted upwards and exhaled volume towards the right.

TABLE 4

MINIMUM REQUIRED SCALE FACTORS FOR TIME, VOLUME, AND FLOW GRAPHICS

Parameter	Resolution Required	Scale Factor
Volume	0.025 L	10 mm/L
Flow	0.100 L/s	5 mm/L/s
Time	0.20 s	2 cm/s

A 2:1 ratio must be maintained between the flow and volume scales, e.g., 2 L/s of flow and 1 L of exhaled volume must be the same distance on their respective axes. The flow and volume scales must be *at least* as shown in Table 4.

Rationale. It was the committee's unanimous opinion that the previous diagnostic recorder requirements of 5 mm/L and 1 cm/s have proven inadequate for judging the quality of an expiratory effort, e.g., terminal events are not detectable (APPENDIX A). For certain applications (for example, for disability determination and legal cases), diagnostic size displays are clearly *not* adequate (26, 30). The U.S. Cotton Dust standard requires ". . . tracings must be stored and available for recall and must be of sufficient size that manual measurements may be made . . ." (31). Also, users will customarily not be able to verify accuracy and stability of spirometers by themselves in the absence of an adequate paper recording.

Recommendation: Correction to BTPS

This statement recommends that diagnostic spirometric studies not be conducted with ambient temperatures less than 17° C or more than 40° C. In part, the rationale for this recommendation is based on problems with finite cooling times of gases in volume-type spirometers (32–34) and the problems of estimating BTPS correction factors for flow devices (35–37). When a subject performs an FVC maneuver, the air leaving the lungs and entering the spirometer is at approximately 33 to 35° C (38, 39) and is saturated with water vapor. Most volume-type spirometers assume instantaneous cooling of the air as it enters the spirometer. However, this is not always the case, and an error in FEV_1 can occur due to the incorrect assumption of instantaneous cooling of the air. For capillary and screen pneumotachometers, the gain is dependent on gas viscosity and increases with increasing temperature. Therefore, a different correction factor is needed between patients and a calibrating syringe and between inspiratory and expiratory maneuvers. In addition, the assumption is usually made that no cooling of the air occurs as the air passes through the flow sensor. This may not be the case, particularly with unheated flow sensors (35). If the expired gas is assumed to be BTPS, an error of about 1% will result. The error will increase if the flow sensor is located further from the mouth and more cooling occurs. In addition, water condensation within or on the surface of a flow sensor may alter its calibration. Depending on environmental temperature, the BTPS correction factor may be as large as 10%. Therefore, the method used to calculate or estimate the BTPS factor can potentially introduce significant errors by the application of an erroneous BTPS correction factor.

Changes in spirometer temperature can be a source of variability; therefore, spirometer temperature should be measured and not assumed to be constant, even over the course of one testing session. Johnson and colleagues (40) found that if ambient temperature was used in BTPS correction and applied to all maneuvers, FEV_1 and FVC measurement errors of up to 6% may occur. When using volume spirometers, they recommend that the temperature of air inside the spirometer should be measured accurately during each breathing maneuver.

Recommendation (Monitoring): Correction to BTPS

For operating simplicity, monitoring devices may use one BTPS correction factor for a range of barometric pressures (altitude) and environmental temperatures. However, the use of a single BTPS correction factor or direct readings at BTPS does not eliminate the requirement to meet the accuracy specifications under BTPS conditions. Therefore, manufacturers must provide appropriate labeling concerning the environmental conditions (ambient temperature and pressure) under which their device will meet the accuracy requirements. If necessary or appropriate, the manufacturer may provide several BTPS correction factors to meet the accuracy requirements over a range of environmental conditions (altitude and temperature).

EQUIPMENT VALIDATION

Recommendation: FVC Validation

The diversity of FVC maneuvers encountered in clinical practice are currently best simulated by the use of the 24 standard waveforms developed by Hankinson and Gardner (17, 41). These waveforms can be used to drive a computer-controlled mechanical syringe or its equivalent for testing actual hardware and software (42, 43) or they can be put into a system in digital form to evaluate *only* the software. It is strongly recommended that spirometry systems be evaluated using a computer-driven mechanical syringe or its equivalent and that the digital forms only be used for evaluating changes in software. APPENDIX C shows the measured values for each of the 24 standard waveforms. The American Thoracic Society also provides these waveforms on floppy disks for an IBM-PC.* Appropriate corrections for using gas at ambient temperature and humidity instead of BTPS may need to be made for some mechanical syringe-spirometer combinations. In addition, precision criteria have been added, and testing of spirometry systems using heated and humidified test gas is recommended.

The accuracy validation limits (tolerance for simulator systems is included in these limits) for volume are: volume (FVC, FEV_1) ± 3.5% of reading or ± 0.070 L, whichever is greater; and average flow ($FEF_{25-75\%}$) ± 5.5% of reading or ± 0.250 L/s, whichever is greater. The error range is expanded from the earlier ATS spirometry recommendation to allow for errors associated with mechanical syringes (42). The precision validation limits are: volume (FVC and FEV_1) 3.5% (range percent) or 0.100 L, whichever is greater; and flow ($FEF_{25-75\%}$) 5.5% or 0.250 L/s, whichever is greater. Mechanical syringes used for validation must be accurate within ± 0.025 L for FVC and FEV_1 and ± 0.100 L/s for $FEF_{25-75\%}$.

Rationale. Testing of spirometry systems using heated and humidified test gas has been added to the validation criteria because of potential problems associated with BTPS correction (32–37). See APPENDIX B for further details.

Recommendation: PEF Validation

PEF instrument designs must be validated using a mechanically driven syringe or its equivalent, using the flow–time waveforms described in APPENDIX D. These waveforms are available on digital media from the ATS. In addition, the mechanically driven syringe must be validated (APPENDIX B) to ensure that it accurately produces these waveforms and corresponding PEFs within ± 2% of reading. The flow–time waveforms in APPENDIX D were chosen to represent a range of peak flows and flow–time signals with various times-to-PEF (time required to go from 0.200 L/s to PEF). The accuracy validation limit for PEF is ± 12% of reading or ± 25 L/min, whichever is greater.

* Available from the American Thoracic Society.

The precision (range deviation) validation limit for PEF is 6% or 15 L/min, whichever is greater.

Rationale. The NAEP (5) recommended the use of a mechanically driven syringe to test and validate the accuracy of peak flow measuring instruments and to assess intra- and interdevice precision. Their recommendations included the use of ATS waveform 24 with various multipliers to achieve different PEFs. One problem with using only waveform 24 is a lack of variability in the shape or rise-time in the waveforms used to test PEF meters. Therefore, the use of several waveforms in the testing and validation of PEF meters to provide a range of PEFs and times-to-PEF (rise-times) is recommended. The waveforms in Appendix D are flow–time waveforms and, therefore, the definition of peak flow obtained from these waveforms is simple to derive. In addition, a volume–time curve for use by the mechanically driven syringe can be obtained from a flow–time curve by simply summing the flow–time values (integrating the flow signal).

The accuracy of the mechanically driven syringe for PEF, ± 2% of reading, was chosen based on current technical feasibility. Current technology of mechanically driven syringes is not sufficient to provide greater accuracies. This is due to the dynamic aspect of peak flow—high frequency content and PEF occurs at a point in the flow–time signal where the acceleration is changing, resulting in potential "overshoot" by a mechanical syringe. In addition, insufficient data are available concerning the accuracy of PEF meters using waveforms with higher frequency content (shorter times-to-PEF). Additional detailed information concerning spirometer testing procedures is contained in Appendices B, C, and D.

Recommendation: MVV Validation

When tested with a pump producing a sinusoidal waveform, the accuracy validation limits of the spirometer used for MVV for flows up to 250 L/min, produced with stroke volumes up to 2 L, are ± 10.5% of reading or ± 20 L/min, whichever is greater. During the testing, the pressure at the mouthpiece must not exceed ± 10 cm H_2O. For volume spirometers, these requirements apply throughout their volume range.

QUALITY CONTROL

Routine equipment preventive maintenance—cleaning, calibration checks, verification, and quality control—is essential to assure accurate spirometry results (44). A spirometry procedure manual is an important base for a quality assurance program. The manual should contain a quality control plan, guidelines for ordering spirometry, guidelines for performing spirometry, and guidelines for reporting spirometry results. See the document, "ATS Quality Assurance for Pulmonary Laboratories," for more details (44).

Recommendation: Technician's Role in Quality Control

Quality control is important to ensure that the laboratory is con-

most important component in successful spirometry is a well-motivated, enthusiastic technician. A recent study has clearly demonstrated the importance of a quality control program with feedback to technicians in obtaining adequate spirometry results (8). A quality control program that continuously monitors technician performance is critical to the collection of high-quality spirometry data. Feedback to the technicians concerning their performance should be provided on a routine basis. This feedback should include, at a minimum: (*1*) information concerning the nature and extent of unacceptable FVC maneuvers and nonreproducible tests; (*2*) corrective action the technician can take to improve the quality and number of acceptable maneuvers; and (*3*) recognition for superior performance by the technician in obtaining good maneuvers from challenging patients/subjects.

Manufacturers are encouraged to include quality control aids in their software packages for spirometers. For example, a calibration logging program may be provided that stores the time and results of routine daily calibration checks. Additionally, the program could issue a warning if an acceptable daily calibration check has not been performed.

Recommendation: Hygiene and Infection Control

This section has been reviewed by the Microbiology Assembly.

The major goal of infection control is to prevent infection transmission to patients/subjects and staff during pulmonary function testing. Two major types of infection transmission are:

1. Direct contact: There is potential for transmission of upper respiratory disease, enteric infections, and blood-borne infections through direct contact. Although hepatitis and HIV contagion are unlikely via saliva, this is a possibility when there are open sores on the oral mucosa, bleeding gums, or hemoptysis. The most likely surfaces for contact are mouthpieces and the immediate proximal surfaces of valves or tubing.
2. Indirect contact: There is potential for transmission of tuberculosis, various viral infections, and, possibly, opportunistic infections and nosocomial pneumonia through aerosol droplets. The most likely surfaces for possible contamination by this route are mouthpieces and proximal valves and tubing.

Prevention:

1. Prevention of infection transmission to technicians exposed to contaminated spirometer surfaces can be accomplished through proper hand washing or use of barrier devices (latex gloves). To avoid technician exposure and cross-contamination, hands should be washed immediately after direct handling of mouthpieces, tubing, breathing valves, or interior spirometer surfaces. Gloves should be worn when handling potentially contaminated equipment if there are any open cuts or sores on technicians' hands. Hand washing should always be performed between patients. Indications and techniques for hand washing during pulmonary function testing have been reviewed by Tablan and coworkers (45).
2. To avoid cross-contamination, reusable mouthpieces, breath-

nique should be flushed at least five times over the entire volume range to facilitate clearance of droplet nuclei. Also, the breathing tube and mouthpiece should be decontaminated between patients. When the open circuit technique is used, only that portion of the circuit through which rebreathing occurs needs to be decontaminated between patients. For example, when a pneumotachometer system is used, either inspiration from the device should be avoided or the resistive element and tubing should be decontaminated between subjects. A disposable sensor is another alternative. When an open circuit technique is used for measurement of only the forced exhalation, without inspiration from the measuring system (either volume- or flow-type spirometers), only the mouthpiece needs to be changed or decontaminated between subjects.

It should be noted that disassembling, cleaning, and/or sensor replacement requires recalibration. If patients do not inspire through the device, there is the disadvantage that test acceptability may be more difficult to assess in the absence of an inspiratory tracing. On the other hand, disassembly, cleaning, or sensor replacement has the disadvantage that recalibration is required. Alternatively, in-line filters may be effective in preventing equipment contamination (46). However, if an in-line filter is used, the measuring system should meet the minimal recommendations for range, accuracy, flow resistance, and back pressure with the filter installed. The influence of commercially available in-line filters on forced expiratory measures, such as the FVC and FEV_1, has not been well characterized.

4. In settings where tuberculosis or other diseases spread by droplet nuclei are likely to be encountered, proper attention to environmental engineering controls, such as ventilation, air filtration, or ultraviolet decontamination of air, should be used to prevent disease transmission.
5. Special precautions should be taken when testing patients with hemoptysis, open sores on the oral mucosa, or bleeding gums. Tubing and breathing valves should be decontaminated before reuse and internal spirometer surfaces should be decontaminated with accepted disinfectants for blood-transmissible agents.
6. Extra precautions may be undertaken for patients with known transmissible infectious diseases. Possible precautions include: (*a*) Reserving equipment for the sole purpose of testing infected patients; (*b*) testing patients at the end of the day to allow time for spirometer disassembly and disinfection; and (*c*) testing patients in their own room or in rooms with adequate ventilation and easily cleaned surfaces.
7. In the absence of evidence for infection transmission during pulmonary function testing, the regular use of in-line filters is not mandated when the precautions described above are followed. However, some spirometric equipment, particularly those incorporated in multi-purpose testing systems, employ valve manifolds that are situated proximal to breathing tubes. These valving arrangements provide internal surfaces on which deposition of expired aerosol nuclei is likely. Given their complexity, they may be difficult to disassemble and disinfect between subjects. To the extent that in-line filters have been shown to remove microorganisms from the expiratory air stream and thus prevent their deposition, presumably as aerosol nuclei on spirometer surfaces (46), their use may be indicated in this setting. The economy of using in-line filters compared with tubing and valve changes depends on the PFT equipment in use. The extent to which measures such as maximum expiratory flow or other instantaneous flows are influenced by the use of in-line filters is undocumented. One study has shown that a low impedance barrier device did not have a significant impact on spirometric indices, such as the forced vital capacity and the FEV_1 (47). If an in-line filter is used during spirometry, interpretation of spirometric indices other than FVC and FEV_1 (e.g., PEF) should allow for the possibility that the filter might affect spirometer performance. The mechanical characteristics of the combined measuring device and filter should meet the minimal recommendations outlined in Table 2. Furthermore, if in-line filters are used, it is recommended that equipment be calibrated with the filter installed. The use of in-line filters does not eliminate the need for regular cleaning and decontamination of spirometric equipment.
8. Manufacturers of spirometric equipment are encouraged to design instrumentation that can be easily disassembled for disinfection.

Rationale. Spirometric equipment has not been directly implicated in the transmission of infections, although there is indirect evidence of infection transmission during pulmonary function testing (PFT). Organisms from the respiratory tract of test subjects can be recovered from PFT mouthpieces and from the proximal surfaces of tubing through which the subjects breathe (48, 49). There is one case report of a tuberculosis skin-test conversion after exposure to a spirometer used to test a patient with documented tuberculosis (50). Likewise, there is circumstantial evidence that contaminated PFT equipment may be implicated in the increasing prevalence of *Pseudomonas* infections among cystic fibrosis patients at one center (51). There is some evidence that pneumotachometer-based systems are less susceptible to bacterial contamination than water-sealed spirometers (52). Finally, it is well documented that community hospital water supplies can be contaminated with Mycobacteria and *Pseudomonas aeruginosa* organisms (53–55). Thus, the potential exists for both patients/subjects and health care workers to deposit microorganisms onto spirometer surfaces (including mouthpieces, nose clips, tubing, and any internal or external machine surface), which could subsequently come into direct or indirect contact with other patients. This does not seem to pose an appreciable threat to patients/subjects with competent immune systems.

It has been argued that immunocompromised patients may require only a relatively small infective dose of either opportunistic organisms or common pathogens. Concerns for the protection of immunocompromised hosts, along with increased public and provider awareness of hospital infection control issues over the past decade, has led many laboratory directors to use in-line filters routinely as a means of reassuring patients and laboratory personnel that adequate consideration has been given to protection. There is no direct evidence that routine spirometry testing poses an increased risk of infection to immunocompromised patients.

Recommendation: Equipment Quality Control

The recommendations that follow are primarily aimed at diagnostic devices.

Attention to good equipment quality control and calibration is an important part of good laboratory practice. Log books of calibration results must be maintained. Documentation of repairs or other alterations that return the equipment to acceptable operation need to be maintained. Dates of computer software and hardware updates or changes must also be maintained.

Volume. The spirometer's ability to accurately measure volume must be checked *at least* daily with a calibrated syringe with a volume of at least 3 L. During industrial surveys or other studies in which a large number of subject maneuvers are done, the equipment's calibration must be checked daily, before testing, and every 4 h during use (44). In circumstances where the temperature is changing (e.g., field studies), more frequent temperature corrections may be needed. Although there is minimal day-to-day variation in volume calibration, daily calibration checking is highly recommended so that the onset of a problem can be determined within 1 day, eliminating needless reporting of false values for several weeks or months and also to help define day-to-day laboratory variability. It is recommended that the calibration syringe be stored and used in such a way as to maintain the exact temperature and humidity of the testing site. This is best accomplished by keeping the syringe in close proximity to the spirometer. In the case of flow-type spirometers where a volume syringe is used to check the instrument, volume calibration checks using different flow rates are recommended. At least three trials where the flow rates are varied between 2 and 12 L/s must be performed (3-L injection times of approximately 1 s, 6 s, and somewhere in between 2 and 6 s).

Syringe Accuracy. The syringe used to check the volume calibration of spirometers must have an accuracy of at least 15 ml or at least 0.5% of full scale (15 ml for a 3-L syringe), and the manufacturer must provide recommendations concerning appropriate syringe calibration intervals. If the syringe has an adjustable variable stop, the syringe may be out of calibration if the stop is reset. Calibration syringes should be leak-tested periodically by trying to empty them with the outlet corked.

Leak Test. Volumetric spirometer systems must be evaluated for leaks on a daily basis (15, 56). The Intermountain Thoracic Society Manual (15) suggests that leaks can be detected by applying a constant positive pressure of 3 cm H_2O or more with the spirometer outlet occluded. Any observed volume change of greater than 10 ml after 1 min is indicative of a leak (15) and needs to be corrected.

Linearity. At least quarterly, volume spirometers must have their calibration checked over their entire volume range (in 1-L increments) using a calibrated syringe (42) or an equivalent volume standard. Flow spirometers must have their linearity determined *at least* weekly and given the current software capabilities, daily linearity checks are reasonable. Flow spirometer linearity can be checked by injecting the volume from a 3-L syringe with several different flows. The linearity check is considered acceptable if the spirometer meets the volume accuracy requirements for all flows and/or volumes tested.

Time. Assessing mechanical recorder time scale accuracy with a stopwatch must be performed *at least* quarterly. An accuracy of within 1% must be achieved. If equipment is changed or relocated (e.g., industrial surveys), calibration checks and quality control procedures must be repeated before initiating further testing.

PEF Meters. Since it is difficult to perform a calibration check of portable peak flow monitoring meters, it is particularly important that the instructions from the manufacturer include information concerning typical instrument lifetimes and methods of recognizing when an instrument is malfunctioning.

Other Quality Assurance Procedures. In addition to calibration with physical standards, the practice of using laboratory personnel as "known subjects" and performing intralaboratory and interlaboratory testing is recommended (44). The ATS has published guidelines for quality assurance in pulmonary function laboratories (44), which can be consulted for specific details.

The use of computers to analyze spirometry has accelerated in the past 10 yr, and this trend is advantageous to obtain accurate spirometry (10, 30). However, testing of commercially available spirometers consistently shows that a major source of errors is in computer software (42). Because of the increased use of computers in pulmonary laboratories and the problems associated with them (42, 57), the ATS has published computer guidelines for pulmonary laboratories (58), which should be followed. Computer software must adhere to ATS recommendations, especially procedural recommendations, contained in this statement. Because of the tremendous improvement in the power and speed of computers and their extensive use in hospitals and clinics, manufacturers should attempt to integrate computers into their spirometry systems. Primary data should be available, allowing independent manipulation of uncorrected values by the user. Listings or descriptions of ATS algorithms should be available (end of test, back-extrapolation, etc.). In addition, some program flexibility should be available to the user, for example, allowing user selection of appropriate reference equations, including the use of user-derived reference equations.

TABLE 5

EQUIPMENT QUALITY CONTROL SUMMARY

Test	Minimum Interval	Action
Volume	Daily	3-L syringe check
Leak	Daily	3 cm H_2O constant pressure for 1 min
Linearity	Quarterly Weekly (flow spirometers)	1-L increments with a calibrating syringe measured over entire volume range (flow spirometers simulate several different flow ranges)
Time	Quarterly	Mechanical recorder check with stopwatch
Software	New versions	Log installation date and perform test using "known" subject

MANEUVER PERFORMANCE RECOMMENDATIONS

Personnel Qualifications

The ATS has made recommendations for laboratory personnel conducting pulmonary function tests (59). High school training was recommended. In addition, the ATS encouraged but did not mandate one or more years of college or equivalent training and a strong background in mathematics. For pulmonary function laboratories, 6 mo of supervised training time is recommended for conducting spirometry. If troubleshooting is to be a part of the laboratory technician's responsibility, a training period of 1 yr is recommended. The ATS recommends that the medical directors must have appropriate training and be responsible for all pulmonary function testing (60).

For industrial/occupational testing, there are training requirements mandated by the National Institute for Occupational Safety and Health (NIOSH), industry, and the ACCP (16, 31, 61). Several excellent training manuals have been prepared for performance of spirometry (15, 16, 31, 62, 63). NIOSH approves the content of spirometry training courses under the U.S. Cotton Dust Standard (16).

Recommendation: VC—Subject Instruction and Maneuver Performance

The VC maneuver may be considered either as an inspiratory vital capacity (IVC), where the subject inhales completely from a position of full expiration, or as an expiratory vital capacity (EVC), where the subject exhales completely from a position of full inspiration. In addition, several spirometer setups are possible using either open or closed circuit techniques with or without rebreathing.

1. A closed circuit technique *without* CO_2 absorption (i.e., using a rolling-sealed or water-sealed spirometer) may be used. Subjects may also rebreathe from the spirometer circuit. Rebreathing is preferable because it allows technicians to better monitor the entire vital capacity maneuver. In the absence of CO_2 absorption and the addition of supplemental oxygen, the maneuver should be brief—fewer tidal volumes before and after the VC maneuver.
2. A closed circuit technique *with* CO_2 absorption and the addition of supplemental oxygen may be used. This system allows

the subject to rebreathe for a longer period of time and establish a better FRC baseline. However, it requires precise replacement of oxygen to avoid shifting the baseline.

3. A modified closed circuit technique (i.e., flow-sensor–based systems where the subject can breathe in and out through the sensor without the need for CO_2 absorption) may be used.
4. An open circuit technique where the subjects may inhale completely before inserting the mouthpiece and exhaling into the spirometer may be used. This may be preferable when hygiene concerns are present.

For all systems, it is important to instruct the subject in the VC maneuver and demonstrate the appropriate technique. It is important that subjects understand they must *completely* fill and empty their lungs.

Standard Procedure Open Circuit Technique. The subject inhales maximally, inserts the mouthpiece just past his/her front teeth, seals his/her lips around the mouthpiece, and blows slowly and evenly until a clear plateau is seen at maximal exhalation or until end-of-test criteria (see sections on FVC and end-of-test criteria) are met. The technician must observe the subject's inhalation to ensure that it is complete and that air is not exhaled while the mouthpiece is being inserted. During the exhalation, the technician should monitor the spirometer volume–time display to ensure that a relatively constant expiratory flow and an adequate end-expiratory plateau is achieved (*see* APPENDIX A for examples of the VC maneuver).

Closed Circuit Techniques. The following procedure should be used when testing is conducted *without* CO_2 absorption (limited oxygen reserve available for test performance). A two-way valve may be useful, allowing the initial tidal volumes to be performed with room air before the subject is connected to the spirometer. The test is begun with quiet breathing, preferably with the subject breathing room air. No more than five tidal volumes should be recorded with the subject rebreathing from the spirometer. The subject should then perform the VC maneuver described below. When CO_2 absorption is not used, returning to FRC after the VC maneuver followed by three tidal volumes may be helpful but is not required.

The following procedure should be used when testing is conducted with CO_2 absorption and oxygen supplementation. The test is begun with quiet breathing. Several tidal volumes should be recorded (minimum of five or until a stable end-expiratory level is observed). The subject should then perform the VC maneuver described below. The end of test is reached when the subject returns to the level of FRC and performs at least three more tidal volumes.

For both procedures, the maneuver is not forced; it is performed in a relaxed manner with the subject using a mouthpiece and a nose clip. The VC maneuver is composed of the subject exhaling completely to residual volume (RV), and completely inhaling to total lung capacity (TLC), and then exhaling to residual volume again. The technician should encourage the subject to reach maximal inhaled and exhaled volumes with a relatively constant flow. Technicians should observe the subject to be certain his/her lips are sealed, that nothing obstructs the mouthpiece, that no leaks occur, and that TLC and RV are reached. The technician should check the volume display to ensure relatively linear inspiratory and expiratory volume curves and adequate maximal inspiratory and expiratory level plateaus. Oxygen should be added to the circuit to precisely counterbalance the absorption of CO_2.

For all techniques, a minimum of two acceptable VC maneuvers should be obtained, with a maximum of four attempts. The largest VC should be reported. Some investigators have reported that the VC is slightly higher than the FVC in normal subjects (64).

TABLE 6

PERFORMANCE OF FVC MANEUVER

Check spirometer calibration
Explain test
Prepare subject
Ask about smoking, recent illness, medication use, etc.
Instruct and demonstrate test to subject
Correct posture with head elevated
Inhale completely
Position mouthpiece (open circuit)
Exhale with maximal force
Perform maneuver
Have subject assume correct posture
Attach nose clip
Inhale completely; the inhalation should be rapid but not forced
Place mouthpiece in mouth and close lips around mouthpiece
Exhale maximally as soon as lips are sealed around mouthpiece*
Repeat instructions as necessary, coaching vigorously
Repeat for a minimum of three maneuvers; no more than eight are usually required
Check test reproducibility and perform more maneuvers as necessary

* D'Angelo and coworkers (65) have reported that PEF and FEV_1 for 13 normal subjects measured in a body plethysmograph are reduced (4% and 5%, respectively) when, during the inspiratory maneuver, there is a 4–6-s pause at TLC before beginning exhalation. Therefore, an excessive pause at TLC should be avoided.

Recommendation: FVC—Subject Instruction and Maneuver Performance

Instruct the subject in the FVC maneuver. The technician should demonstrate the appropriate technique (Table 6). Have the subject inhale from FRC and then, if using the open circuit method, insert the breathing tube into his/her mouth, making sure his/her lips are sealed around the mouthpiece, and begin the FVC maneuver with minimal hesitation (65). It is *imperative* that the subject have a complete inhalation before beginning the forced exhalation. Prompt the subject to "blast," not just "blow," the air from their lungs, then continue to encourage him/her to fully exhale. Throughout the maneuver, enthusiastically coach the subject by word and body language. It is particularly helpful to observe the subject and the chart recorder or computer display during the test to better ensure maximal effort. Perform a *minimum* of three acceptable FVC maneuvers. If a subject shows large variability (FVC and/or FEV_1) between expiratory maneuvers (> 0.2 L), reproducibility criteria may require that up to but usually no more than eight maneuvers be performed. Volume–time or flow–volume curves from the best three FVC maneuvers must be retained. See Figure 3 and the section on acceptability and reproducibility for further clarification.

Recommendation (Monitoring): PEF—Subject Instruction and Test Performance

Since PEF is both effort- and volume-dependent, maximum subject cooperation is essential. Since an optimal peak flow is usually reached in about one-tenth of a second, patients must be encouraged to perform the expiratory maneuver as vigorously as possible. The subject should not cough and a prolonged exhalation is unnecessary (1 to 2 s is adequate).

When implementing unobserved self-administered PEF measurements, it is essential that:

1. The subject should be taught how to use the peak flow meter properly by someone skilled with the procedure. Trained personnel should observe the subject's performance both initially and on repeat visits.
2. The subject should be taught how and when to record PEF measurements, along with other pertinent information, such as symptoms.
3. The subject should be instructed about what action to take if PEF falls.

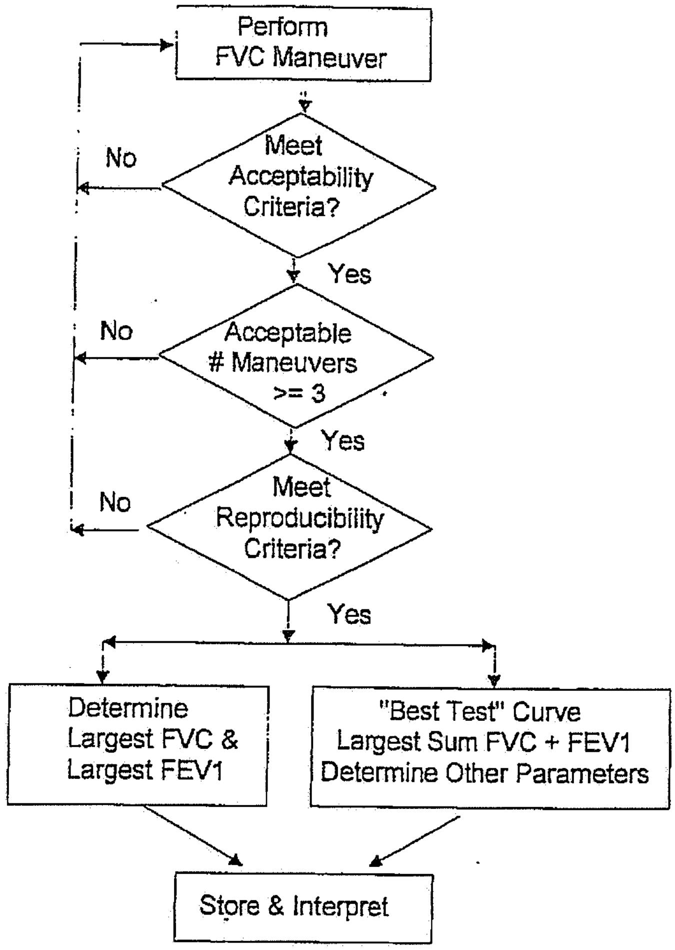


Figure 3. Flow-chart diagram of FVC spirometry testing.

TABLE 7

PERFORMANCE OF PEAK FLOW MANEUVER

Explain and demonstrate the test*
Zero the PEF monitor, if necessary
Stand up straight
Inhale completely; the inhalation should be rapid but not forced
Place PEF monitor in mouth and close lips around mouthpiece†
Exhale with maximal force‡ as soon as lips are sealed around mouthpiece§
Write down results
Repeat two more times (three total)
Record all three values

* Not necessary if at home.

† Nose clips are not necessary.

‡ Make sure subject understands to make full use of respiratory muscles, not just use the diaphragm as a "toot" or "mouth" maneuver.

§ D'Angelo and coworkers (65) have reported that PEF is reduced when, during the inspiratory maneuver, there is a 4–6-s pause at TLC before beginning exhalation. It is not known if similar changes will be observed with portable peak flow meters.

Recommendation: FVC—Satisfactory Start-of-Test Criteria

To achieve accurate "time zero" and ensure that the FEV_1 comes from a maximal effort curve, the extrapolated volume must be less than 5% of the FVC or 0.15 L, whichever is greater. See Figure 2 for an example and explanation of back extrapolation. In the example shown, the extrapolated volume is 0.16 L or 8%. In general, back-extrapolated volume should be measured on any curve with a perceptible extrapolated volume. Provisions for rapid computerized feedback to the technician when these criteria are not met are encouraged.

The committee discussed the possible use of time-to-PEF as a measure of the subject's performance early in the FVC maneuver. However, the committee felt there were insufficient data on which to base a clear recommendation, and additional research is needed. When conducting research on assessment of the subjects' correct performance of FVC maneuvers, investigators are encouraged to measure the time-to-PEF or rise-time of peak flow in addition to other quality assessment parameters. The rise-time of peak flow is defined as the time required for expiratory flow to rise from 10% to 90% of the maneuver's peak flow. Although use of other measures of acceptable efforts have been described and may be useful (8, 66), they are not recommended at this time.

Rationale. A very slow start with a low peak flow will result in a greater than allowable extrapolated volume (Figure 2) (1, 67–69). In addition, the FEV_1 from a submaximal effort can be either smaller than those obtained when a maximal effort is performed because the subject fails to reach a maximal TLC, or larger due to less dynamic compression of airways in subjects where airways are relatively more collapsible. Recent experience in large epidemiologic studies (8) suggests that use of time-to-PEF and PEF reproducibility may minimize most of these problems in the majority of subjects. However, at this time, it is not recommended that maneuvers be eliminated because of a low PEF or PEF rise-time, but only because of an excessively large extrapolated volume.

Recommendation: FVC—Minimum Exhalation Time

A minimum exhalation time of 6 s (length of maximum expiratory effort), unless there is an obvious plateau in the volume-time curve display, is required to obtain maximal FVC results. There are instances (e.g., the testing of children, young adults, and some restricted patients) where shorter exhalation times are acceptable.

Recommendation: FVC—End-of-Test Criteria

To obtain an optimal effort, it is important that subjects be verbally exhorted to continue to exhale air at the end of the maneuver. End-of-test criteria are used to identify a reasonable FVC effort. Recommended end-of-test criteria are:

1. The subject cannot or should not continue further exhalation. Although subjects should be encouraged to achieve their maximal effort, they should be allowed to terminate the maneuver on their own at any time, especially if they are experiencing discomfort. The technician should also be alert to any indication the patient is experiencing discomfort and should terminate the test if a patient is becoming uncomfortable.

OR

2. The volume-time curve shows an obvious plateau. This criterion is based on no change in volume for *at least* 1 s after an exhalation time of *at least* 6 s (10 s is optimal). "No change in volume" is defined as the minimal detectable volume of the spirometer. To meet ATS criteria, the minimal detectable volume for spirometers must be 0.030 L or less.

OR

3. The forced exhalation is of reasonable duration. For patients with airways obstruction or older subjects, exhalation times longer than 6 s are frequently needed to reach a plateau. Many would not reach a plateau even with a 20-s exhalation. However, exhalation times greater than 15 s will rarely change clinical decisions. *Multiple* prolonged exhalations (longer than 6 s) are seldom justified and may cause lightheadedness, syncope, undue fatigue, and unnecessary discomfort. In such patients, a slow or unforced VC maneuver (previously described) may provide a more appropriate denominator for calculation

of the $FEV_1/VC\%$. Manufacturers should note that several of the 24 test waveforms have durations longer than 20 s.

Achieving an end-of-test criterion is one measure of maneuver acceptability. Maneuvers that do not meet an end-of-test criterion should not be used to satisfy the requirement of three acceptable maneuvers. However, early termination is not by itself a reason to eliminate a maneuver from further consideration. Information such as FEV_1 and FEV_3 may be valid (depending on the length of exhalation) and should be reported from these early terminated maneuvers. When the subject does not exhale completely, the volume accumulated over a shorter period of time (e.g., 4 s) may be used as an approximate surrogate for FVC. In such cases, the volume label should reflect the shorter exhalation time (e.g., FEV_4 for a 4-s exhalation).

Recommendation: VC and FVC—Maximum Number of Maneuvers

Although there may be some circumstances in which more than eight consecutive FVC maneuvers may be needed, eight maneuvers is considered a practical upper limit for most subjects. After several forced expiratory maneuvers, fatigue begins to take its toll on subjects, and thus on their spirometric parameters, so additional maneuvers would be of little added value. In addition, some subjects with asthma may exhibit spirometry-induced bronchospasm. Ferris and associates (70) and Kanner and colleagues (71) have reported that for adults and children, eight maneuvers is a practical upper limit. For VC, four is considered a practical upper limit. Because of the potential for muscular fatigue and volume history effects, it is preferable that VC maneuvers be performed before FVC maneuvers.

Recommendation (Monitoring): PEF—Number of Trials

The subject must perform and record a minimum of three trials.

Recommendation: VC and FVC—Environmental Conditions

Spirometric testing with ambient temperatures less than 17° C or more than 40° C may pose problems. Ambient temperature must *always* be recorded and reported to an accuracy of ± 1° C. In situations where the ambient air temperature is changing rapidly (> 5° C in less than 30 min), continuous temperature corrections should be made. Spirometer users should be aware of the problems with testing done at lower temperatures, which in some subjects can cause airflow limitation. Due to other technical reasons, 17° C is judged to be an acceptable and reasonable lower limit (32–38, 72) for ambient temperature. Ranges of barometric pressures that are acceptable for the spirometer must be published by the manufacturer.

Rationale. There is evidence that some subjects may develop airflow limitation with the inhalation of very cold air. Therefore, spirometry should not be conducted when the ambient temperature is cold enough to induce airflow limitation.

Studies also point out the problem of finite cooling times of gases in volume-type spirometers and their associated tubing (32–35) when BTPS correction techniques usually assume instantaneous cooling. In one of these studies, it was found that a 7.7 to 14% error in FEV_1 results if the volume-type spirometer is at an ambient temperature of 3° C and the standard BTPS correction is used. This error is less if the spirometer is warmer (nearer body temperature) (32). As a result, 17° C was judged to be an acceptable and reasonable lower limit.

Complexities related to temperature are also encountered with flow-measuring devices (34–38). Air exhaled from the mouth is estimated to be 33 to 35° C (36, 38, 39). If any connecting tubing is used between the mouthpiece and the flow sensor, the exhaled gas will experience a variable amount of cooling if the room temperature is not at approximately 33° C. Details of the cooling pattern for many types of flow spirometers have not been studied, but they may result in errors similar to those for volume devices (34–38).

Because not all spirometers are used at sea level (blood pressure = 760 mm Hg), the range of barometric pressures allowed by the spirometer and its associated computational equipment must be specified by the manufacturer.

Recommendation: VC and FVC—Use of Nose Clips

In most people, not wearing nose clips does not appreciably influence the FVC when using the open circuit technique. However, some people breathe through the nose and the use of nose clips is encouraged, especially when performing a slow VC maneuver. Nose clips must be used if a closed circuit technique with carbon dioxide absorption is used.

Recommendation: VC and FVC—Sitting Versus Standing

Testing may be done either in the sitting or standing position. Indication of position is necessary on the report (1, 73). The standing position may not be appropriate in some circumstances, such as in hospitals where many patients may not be able to tolerate the standing position, especially when making forced maneuvers. The selection of the position for testing is, therefore, an individual one. If the standing position is used, an appropriately shaped chair should be placed behind the patient/subject so he/she can be quickly and easily eased into a sitting position if he/she becomes light-headed during the maneuver.

Rationale. Studies by Townsend show that for adults there are significantly larger FEVs in the standing position than in the sitting position (73). The earlier ATS recommendation indicates that in children, VC is greater when standing (1).

Recommendation (Monitoring): PEF—Nose Clips and Subject Position

Nose clips are not necessary when using PEF meters. Although the test can be conducted while sitting, the standing position is preferred.

Rationale. Because the PEF is dependent on a complete inhalation and an exhalation with maximal force, the standing position is preferred.

Bronchodilator Testing. Spirometry is often performed before and after inhalation of bronchodilators (or bronchoconstrictors) from a metered dose inhaler (MDI) or nebulizers. Although specific recommendations are beyond the scope of this document, it should be remembered that this is a complex procedure. Factors that can significantly affect a patient's response include: (*1*) activity, dose, and airway deposition of the medication; (*2*) recent prior medication; (*3*) timing of the postmedication maneuver; (*4*) choice and variability of the measurement used to detect a response; and (*5*) the method of calculating the magnitude of change after administering the bronchodilator.

MEASUREMENT PROCEDURES

Measurement

Spirometric variables should be measured from a series of *at least* three acceptable forced expiratory curves.

Recommendation: VC and FVC—Test Result Selection/Reporting of Results

The largest VC should be reported from all acceptable curves, including the forced maneuvers (FVC). The largest FVC and the largest FEV_1 (BTPS) should be recorded after examining the data from all of the acceptable curves, even if they do not come from the same curve. Other measures, such as the $FEF_{25-75\%}$ and the instantaneous expiratory flows, should be obtained from the single curve (1, 2, 15) that meets the acceptability criteria and gives the largest sum of FVC plus FEV_1 (best test).

Recommendation (Monitoring): PEF—Test Result/Reporting of Readings

Although all readings are recorded, the highest reading at any testing session (minimum of three trials) should be used in trend analysis. All readings are recorded to allow the comparison of the trials to evaluate reproducibility and to detect possible maneuver-induced bronchospasm.

Rationale. Since the PEF is effort-dependent, the highest reading should be used. This is consistent with the current recommended selection method for FVC and FEV_1.

ACCEPTABILITY AND REPRODUCIBILITY

Recommendation: VC and FVC—Maneuver Acceptability

For FVC measurements, acceptability must be determined by ascertaining that the recommendations outlined previously in the section on performing the FVC test are met. APPENDIX A contains examples of unacceptable volume–time and corresponding flow–volume curves. In review, these acceptability criteria are: (*1*) satisfactory start-of-test; (*2*) minimum FVC exhalation time of 6 s; and (*3*) end-of-test criteria. In addition, the technician should observe that the subject understood the instructions and performed the maneuver with a maximum inspiration, with a good start, with a smooth continuous exhalation, with maximal effort, and *without:*

1. An unsatisfactory start of expiration, characterized by excessive hesitation, false start, or extrapolated volume of greater than 5% of FVC or 0.15 L, whichever is greater (Figure 2).
2. Coughing during the first second of the maneuver, thereby affecting the measured FEV_1 value, or any other cough that, in the technician's judgment, interferes with measurement of accurate results (APPENDIX A, Figures 2A and 2B).
3. Early termination of expiration. A plateau in the volume–time curve should be observed, as defined by no change in volume for at least 1 s or a reasonable expiratory time. In a *normal* young subject this would be before completion of the breath—*usually* less than a 6-s maneuver. In an obstructed or older healthy subject, a longer expiratory time is required to reach a plateau (2, 74, 75) (APPENDIX A, Figures 3A and 3B). However, *multiple* prolonged exhalations (longer than 6 s) are seldom justified.
4. Valsalva maneuver (glottis closure) or hesitation during the maneuver that causes a cessation of airflow (APPENDIX A, Figures 4A and 4B).
5. A leak (APPENDIX A, Figures 5A and 5B).
6. An obstructed mouthpiece (e.g., obstruction due to the tongue being placed in front of the mouthpiece or false teeth falling in front of the mouthpiece).

For VC measurements, all of the above requirements should be met with the exception of those related to the forced nature of the effort. In addition, plateaus in the volume–time display should be reached at both the maximal inspiratory and expiratory volumes.

Computer-based systems that provide feedback to the technician when the above conditions are not met are desirable. The reporting format should include qualifiers indicating the acceptability of each maneuver. However, it cannot be overemphasized that failure to meet these criteria does not necessarily invalidate the maneuver, since for some subjects this is their best performance. Further, such maneuvers should be retained, since these maneuvers may contain useful information.

A flow chart outlining how acceptability and reproducibility criteria are to be applied is shown in Figure 3.

Recommendation: VC and FVC—Test Result Reproducibility

As a goal during test result performance, the largest FVC (or VC) and second largest FVC (or VC) from acceptable maneuvers must not vary by more than 0.2 L. In addition for forced exhalations, the largest FEV_1 and the second largest FEV_1 must not vary by more than 0.2 L. The 0.2 L reproducibility criteria are a change from the ATS 1987 Spirometry Statement and are intended to provide an equal assessment of test reproducibility independent of lung size. However, these criteria are only goals during data collection; therefore, an immediate change in spirometry data collection software is not warranted.

The reproducibility criteria are used as a guide to whether more than three acceptable FVC maneuvers are needed; these criteria are *not* to be used for excluding results from reports or for excluding subjects from a study. Labeling results as being derived from data that do not conform to the reproducibility criteria stated above is encouraged (especially when the data suggest that bronchospasm was triggered by the FVC maneuver). In addition, the reproducibility criteria are minimum requirements and many subjects should be able to provide FVC and FEV_1 reproducibility well below 0.2 L. The acceptability criteria must be applied before the reproducibility criteria (Figure 3). Unacceptable maneuvers must be discarded before applying the reproducibility criteria.

The only criterion for unacceptable subject performance is fewer than two acceptable curves. No spirogram should be rejected solely on the basis of its poor reproducibility. Reproducibility of results should be considered at the time of interpretation. Use of data from maneuvers with poor reproducibility is left to the discretion of the interpreter. In addition, use of data from unacceptable maneuvers due to failure to meet the end-of-test requirements is left to the discretion of the interpreter.

Rationale. Several epidemiologic studies (67–69) have shown that the elimination of data from subjects who fail to meet the ATS reproducibility criteria may result in a population bias by excluding data from subjects who have abnormal lung function. Pennock and colleagues (76) have reported that subjects with obstruction have greater coefficients of variation than do normal subjects. Therefore, these subjects are more likely to be unable to meet the ATS minimum reproducibility criteria. The reproducibility criteria have been simplified to eliminate confusion. If acceptability criteria are not applied before the reproducibility criteria, a passive exhalation maneuver will often be labeled as the best test maneuver because it may give the largest sum of FVC and FEV_1.

The calculation of the FVC and FEV_1 reproducibility presents no problem for a computer; however, the need for rapid determination of FEV_1 during the testing session presents a recognized logistics problem if results are hand-measured and calculated. Changing to 0.2-L criterion does simplify this calculation.

Changing the reproducibility criteria to a minimum value of 0.2-L is based on evidence that within subject variability of FVC and FEV_1 is not dependent on body size. The use of a 5% or 100-ml criterion has been shown to result in more individuals of short stature being classified as nonreproducible. In contrast, a 0.2-L fixed volume criterion provides a commensurable level of difficulty for all subjects, regardless of age or height (lung volume) (77). Regardless of the reproducibility criterion for FVC or FEV_1, it should be used as a goal during data collection. Therefore, continued use of the previous criteria (5% or 0.1 L, whichever is greater) during an interim period should have little practical impact on spirometry results.

Recommendation: PEF—Maneuver Acceptability and Reproducibility

PEF values for each maneuver must be recorded in the order in which they occur. This information will be useful in detecting possible test (maneuver)-induced bronchospasms.

TABLE 8

ACCEPTABILITY AND REPRODUCIBILITY CRITERIA: SUMMARY

Acceptability criteria

Individual spirograms are "acceptable" if:

- They are free from artifacts (*see* APPENDIX A for examples)
  - Cough or glottis closure during the first second of exhalation
  - Early termination or cutoff
  - Variable effort
  - Leak
  - Obstructed mouthpiece
- Have good starts
  - Extrapolated volume less than 5% of FVC or 0.15 L, whichever is greater; *OR*
  - Time-to-PEF of less than 120 ms (optional until further information is available)
- Have a satisfactory exhalation
  - 6 s of exhalation and/or a plateau in the volume–time curve; *OR*
  - Reasonable duration or a plateau in the volume–time curve; *OR*
  - If the subject cannot or should not continue to exhale

Reproducibility criteria

After three acceptable spirograms have been obtained, apply the following tests:

- Are the two largest FVC within 0.2 L of each other?
- Are the two largest FEV_1 within 0.2 L of each other?

If both of these criteria are met, the test session may be concluded.

If both of these criteria are not met, continue testing until:

- Both of the criteria are met with analysis of additional acceptable spirograms; *OR*
- A total of eight tests have been performed; *OR*
- The patient/subject cannot or should not continue

Save at a minimum the three best maneuvers

Rationale. Unlike the FEV_1 obtained from routine spirometry, PEF measurements are more variable, and the measurement is often conducted in patients with high variability in their PEF. Although there may be some benefit from using PEF reproducibility to improve a subject effort, no specific reproducibility criterion is recommended at this time.

REFERENCE VALUES, INTERPRETATION STANDARDIZATION, AND CLINICAL ASSESSMENT

Clinical/Epidemiologic Considerations

Whether the spirogram results are to be used for clinical or epidemiologic purposes, the following recommendations apply.

Since the last standards were issued in 1987, a detailed statement on selection of reference values and interpretation of lung function tests has been published (3). The interpretation of spirometry involves two tasks: (*1*) The classification of the derived values with respect to a reference population and assessment of the reliability of the data; and (*2*) The integration of the spirometric values into the diagnosis, therapy, and prognosis for an individual patient. The first task is ordinarily the responsibility of the laboratory director or a designee and serves not only to communicate information to referring health care providers but also is an important aspect of laboratory quality control. The second task is ordinarily the responsibility of the physician requesting the studies and is performed within the context of patient care.

It is the responsibility of the medical director to develop explicit procedures for interpretation of spirometry and to select appropriate reference values. The procedures for interpretation and reference values may legitimately vary from laboratory to laboratory depending upon geographic location and the characteristics of the population being tested. In a setting where large numbers of healthy individuals are being screened for abnormality and the prevalence of disease is low, it is appropriate to set the threshold for abnormality at a higher level than in a setting where most individuals are referred because of symptoms or disease. In the latter case, where the prevalence of disease is high, an appropriate standard would be set to a more sensitive threshold for abnormality. The interpretative strategy should also take into consideration the consequences of false-positive and false-negative errors. Accordingly, no specific guidelines for interpretative procedures are recommended that would be applicable to all laboratories. More important, however, is that there be a consistent approach to the interpretation of lung function tests within a single laboratory. Therefore, referring physicians will not infer a change in the condition of the patient from a change in interpretation when it is the result of a change in the approach of the interpreting physician.

In providing the referring physician with an interpretation of spirometry results, it is also important to comment on deviations of the data from the guidelines for acceptability and reproducibility set forth herein. Although a spirometry session may not meet all of the guidelines, it may provide important clinical information and should be reported with appropriate qualification. Although some individuals display negative effort dependence, submaximal efforts usually lead to underestimation of the maximal effort values (28). Suboptimal efforts may be adequate to assist clinical decisions, where it can be judged that the recorded values underestimate true lung function.

Acknowledgment: The Committee thanks those who have provided input to this update of the Standardization of Spirometry. Special thanks go to the original participants of the Update Workshop, whose valued input was sought and used.

External reviewers: Scott T. Weiss, M.D., M.S., Gary R. Epler, M.D., and James R. Hansen, M.D.

APPENDIX A

Sample Spirograms

The sample spirograms shown in this appendix are from actual individuals and represent a few illustrations of acceptable and unacceptable maneuvers. It is imperative that the technician administering the test be capable of recognizing these anomalies and take appropriate corrective action — proper coaching. During the interpretation process, the reviewer may decide to include a maneuver that may have been considered unacceptable during test performance. As with the reproducibility criteria, some judgment must be made concerning what is an unacceptable maneuver. This decision will be based on the number of curves available, the disease pattern observed or expected for the individual, etc. However, the technician's action taken during the data collection stage of the process should almost always be to obtain additional maneuvers combined with effective coaching of the individual.

Figures A1a and A1b are volume–time and corresponding flow–volume samples that are acceptable spirograms from the draft NIOSH spirometry manual (78). In these spirograms, the individual exhibited a maximal effort for the entire maneuver, exhaling for at least 6 s with a greater than 1 s plateau in the volume–time curve. Figure A1a illustrates the relative expansion of the last portion of the FVC maneuver associated with a volume–time curve display. In contrast, Figure A1b illustrates the relative expansion of the initial portion of the FVC maneuver associated with a flow–volume curve display. Notice in the flow–volume curve (Figure A1b) it is more difficult to determine that the individual produced an acceptable plateau than in the volume–time curve display.

Figures A2a and A2b illustrate an unacceptable spirogram due to a cough during the first second of exhalation. Notice that the cough, which occurs at approximately 3.0 to 3.5 L, is very apparent in the flow–volume curve but is more difficult to detect in the volume–time curve. The anomalies seen in the volume–time curve at approximately 5.0 and 5.5 L could be slight coughs or variable effort, but occurred after the first second of exhalation.

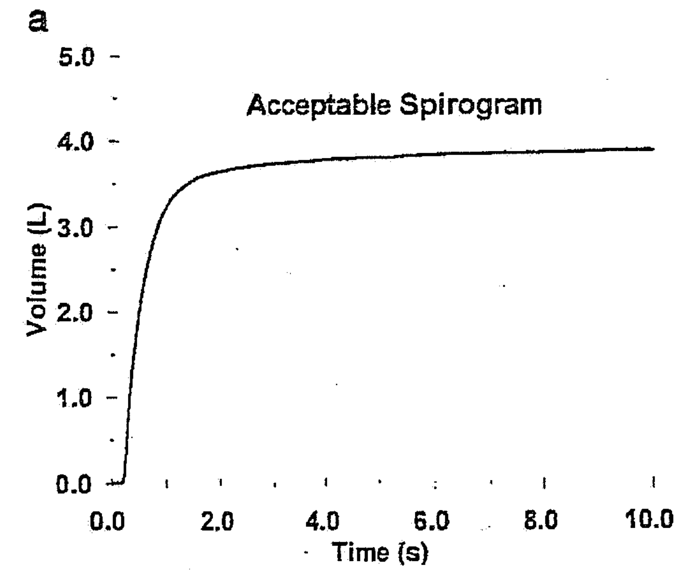


Figure A1a. Acceptable volume–time spirogram.

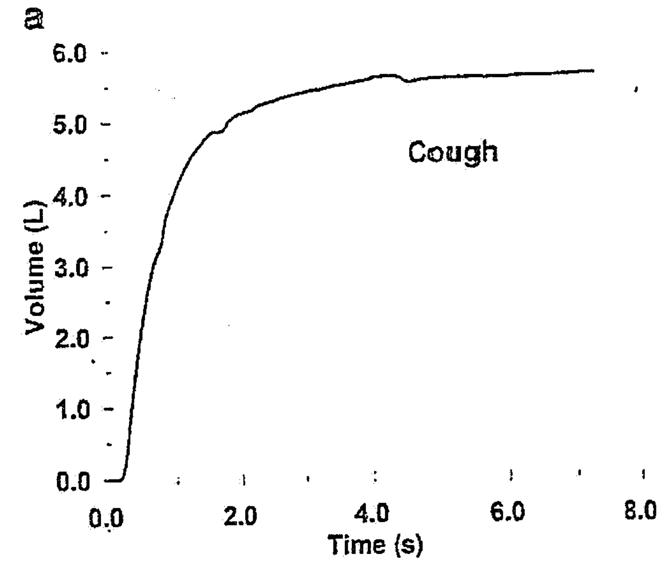


Figure A2a. Volume–time spirogram with a cough during the first second of exhalation.

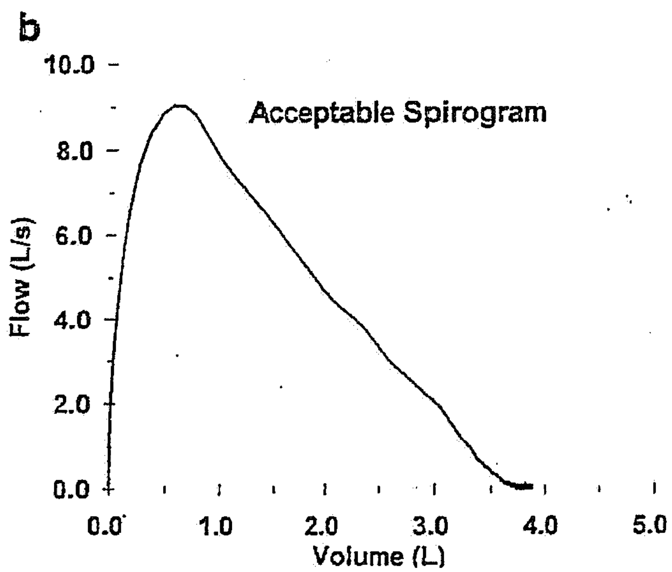


Figure A1b. Acceptable flow–volume spirogram.

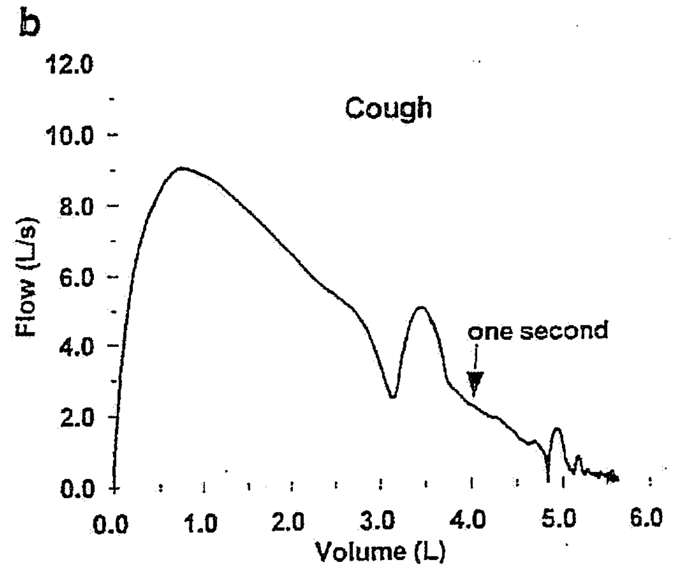


Figure A2b. Flow–volume spirogram with a cough during the first second of exhalation.

Although the fluctuations in flow observed in the flow–volume curve in Figure A2b are reasonably large, they may not result in a significantly different FEV_1. Therefore, the FEV_1 from this curve may be valid, particularly if all other curves are unacceptable. Regardless, when the technician observes the spirograms in Figures A2a and A2b, additional maneuvers should be obtained from the individual.

Figures A3a and A3b illustrate an unacceptable spirogram due to a variable effort or cough during the first second of exhalation and early termination of the maneuver. The anomaly observed at 1 L of exhalation is apparent on both the volume–time and flow–volume curves.

The duration of the anomaly and the fact that the flow immediately following the anomaly does not exceed the expected flow–volume envelope suggest that the anomaly is a variation in effort instead of a cough. The early termination is less apparent on the flow–volume curve. However, on the volume–time curve, it is apparent that the individual failed to exhale for 6 s and there is no 1-s plateau of the volume–time curve.

Figures A4a and A4b illustrate unacceptable sample spirograms due to an abrupt termination of flow at the end of the maneuver, possibly the result of the individual closing his/her glottis. Notice in Figure A4a that the volume–time curve plateau occurs abruptly at approximately 2.2 s where the volume remains constant for the remainder of the maneuver. In Figure A4b, the flow–volume curve exhibits an abrupt decrease in flow at the end of the maneuver.

Figures A5a and A5b illustrate unacceptable sample spirograms due to a leak in the volume-type spirometer or spirometer hose. This leak is approximately 50 ml/s and produces an approximate 300-ml loss in volume over the 6-s exhalation produced by this individual. Notice that the leak is very apparent on the volume–time curve and perhaps less apparent on the flow–volume curve. At the end of the maneuver when the leak is most

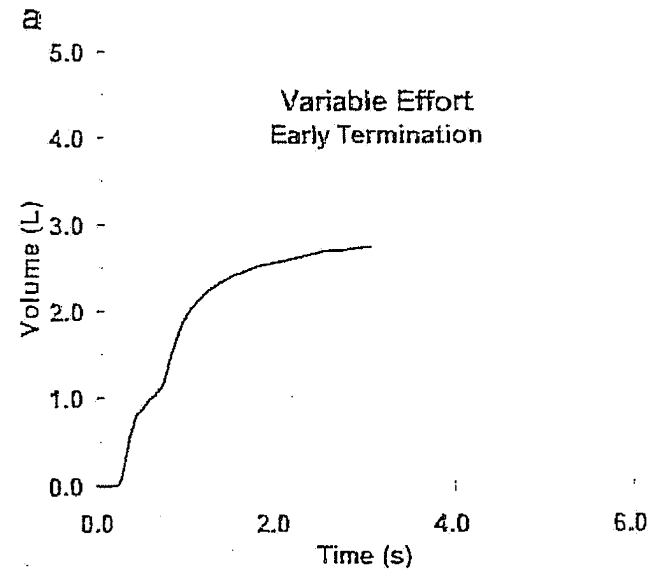


Figure A3a. Unacceptable volume–time spirogram due to variable effort and early termination.

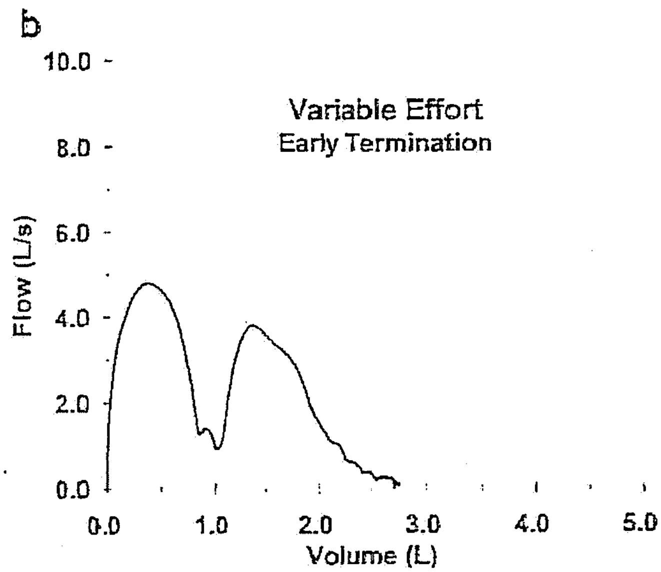


Figure A3b. Unacceptable flow–volume spirogram due to variable effort and early termination.

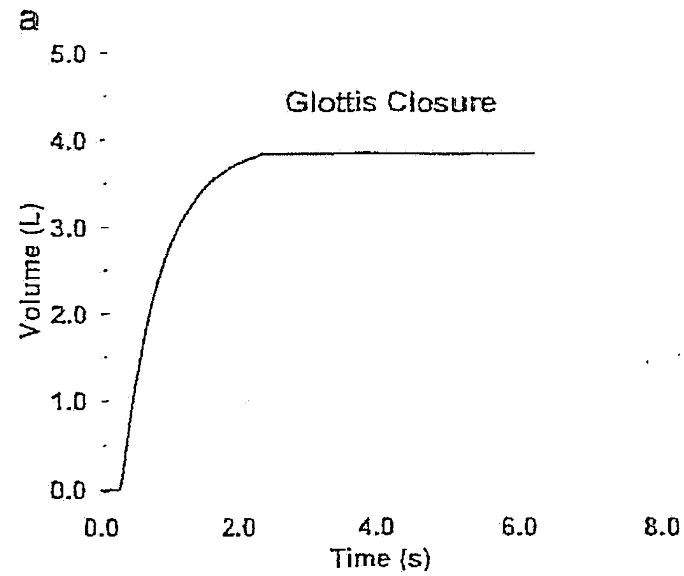


Figure A4a. Unacceptable volume–time spirogram due to possible glottis closure.

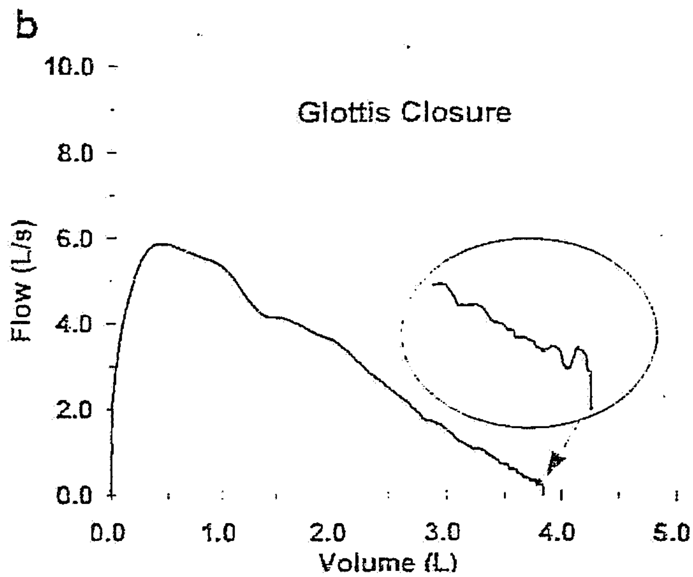


Figure A4b. Unacceptable flow–volume spirogram due to possible glottis closure.

apparent, the flow is slightly negative and volume is decreasing (*see* insert in Figure A5b, short line moving to the left below the zero flow line). If a spirometry system display does not display negative flows, then the leak would be even less apparent on the flow–volume curve.

Figures A6a and A6b illustrate acceptable sample spirograms for an individual with mild airways obstruction ($FEV_1/FVC\%$ = 67%). Notice the relatively small change in volume after 10 s of exhalation (Figure A6a) and the corresponding relative low flow (Figure A6b) at the end of the maneuver.

In addition to requiring three acceptable maneuvers, the reproducibility criteria for FVC and FEV_1 should be met as a goal during test performance. Figure A7a illustrates the volume–time curve and Figure A7b the corresponding flow–volume curve for a 22-yr-old, healthy female. In these figures, the subject did not meet the minimum reproducibility criteria for both the FVC and FEV_1 despite performing three acceptable maneuvers. The second largest FVC was 0.43 L (10%) lower than the largest, and the second largest FEV_1 was 0.37 L (12.1%) lower than the largest FEV_1. Therefore, at least one additional maneuver should be performed by this subject in an attempt to meet the FVC and FEV_1 reproducibility criteria. The most likely cause of this pattern (nonreproducible tracings but good initial effort) is a failure to achieve a maximal inhalation before performing the FVC maneuver.

Figures A8a and A8b illustrate a reproducible test with three acceptable maneuvers. Figure A8a displays the three acceptable volume–time curves, and Figure A8b displays the corresponding flow–volume curves. These maneuvers were obtained from an 80-yr-old male with an $FEV_1/FVC\%$ = 61.7%. Notice that the curves are very reproducible even though the subject required approximately 20 s to reach his final volume or FVC.

Figure A9 shows a sample VC maneuver for a normal subject. This subject starts the test with several tidal volumes through

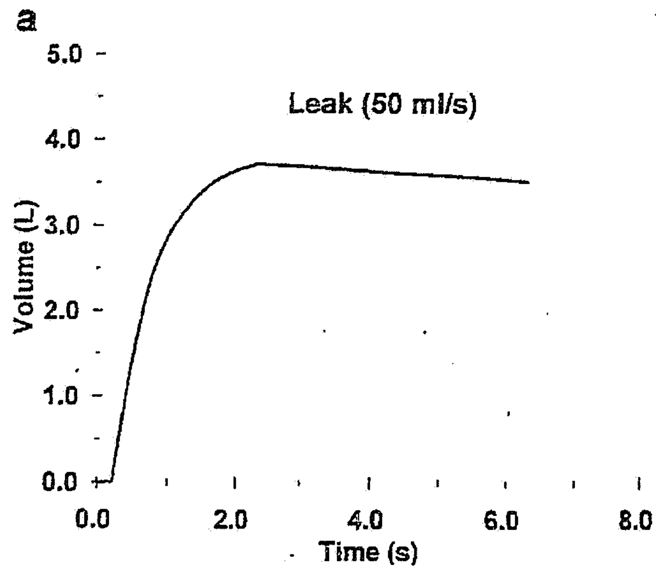


Figure A5a. Unacceptable volume–time spirogram due to a leak.

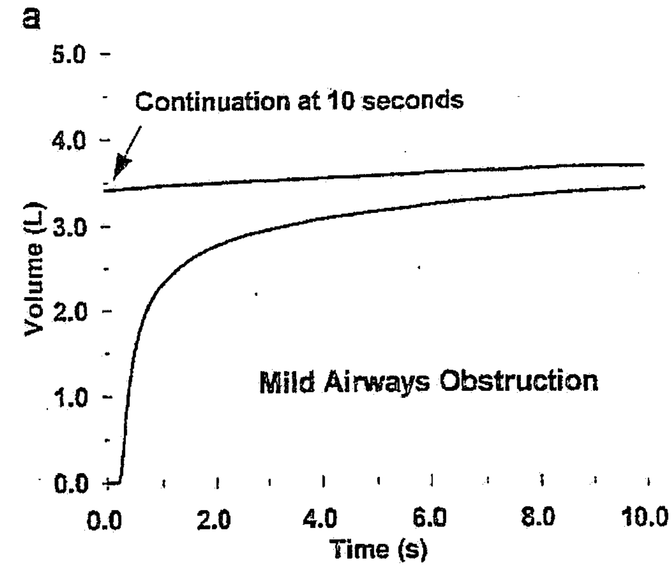


Figure A6a. Acceptable volume–time spirogram for an individual with mild airways obstruction.

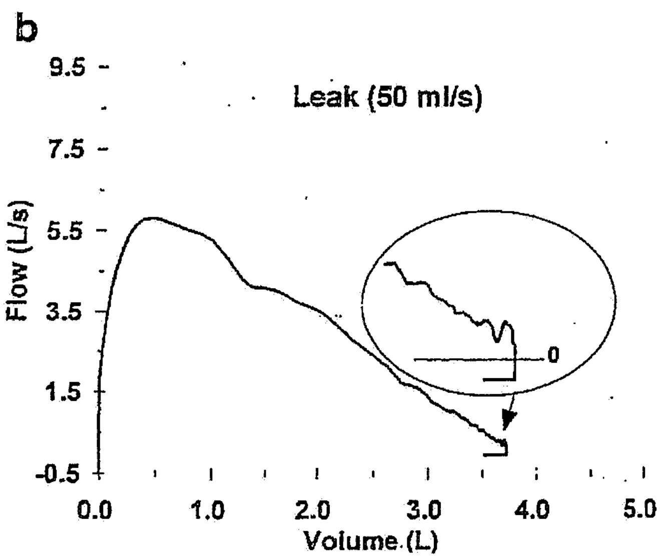


Figure A5b. Unacceptable flow–volume spirogram due to a leak.

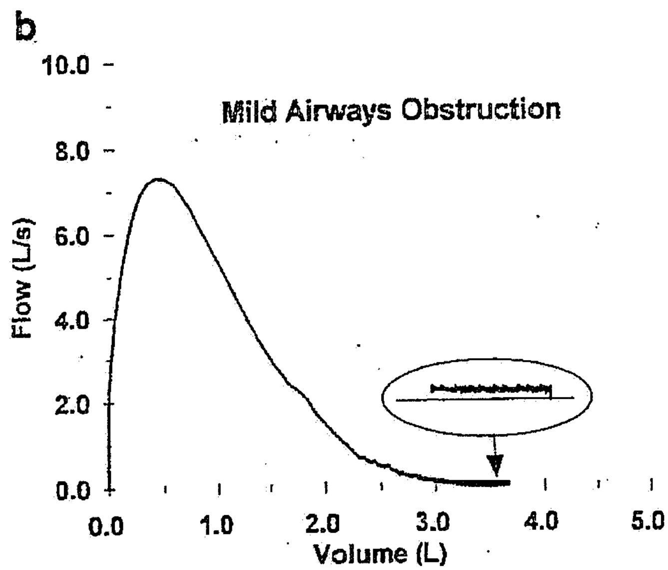


Figure A6b. Acceptable flow–volume spirogram for an individual with mild airways obstruction.

a valve opened to room air to become accustomed to breathing on the mouthpiece. The subject is then connected to the spirometer, where several additional tidal volumes are recorded. The subject then completely inhales to total lung capacity (TLC) and slowly exhales to residual volume (RV), making sure to completely inhale to TLC and exhale to RV. After reaching RV, the subject returns to FRC, where several tidal volumes are again obtained before the subject comes off the mouthpiece. Notice the plateaus at TLC and RV, indicating that the subject has completely inhaled and exhaled.

Figure A10 shows a sample VC maneuver for a subject with severe airways obstruction. The identical maneuver for the normal subject shown in Figure A9 is repeated for this subject with severe airways obstruction. However, the tidal volumes of the subject with severe airways obstruction are much more rapid and the subject requires a longer exhalation time to reach RV, as long as 25 s. Notice that as with the normal subject, a plateau in the volume–time curve is obtained at both TLC and RV. This indicates that the subject has completely inhaled and exhaled. Also notice that the subject has some difficulty in obtaining a stable FRC after the VC maneuver, probably due to gas trapping.

APPENDIX B

Spirometer Testing Guidelines

The following testing guidelines should be used when evaluating new spirometer designs and when changes have been made to spirometer hardware or software. For production testing, the use of a smaller set of test waveforms may be appropriate. The spirometer selected for testing should be a "production" model and not one that was specifically selected because of any extraordinary calibration efforts. Once testing has begun, the device be-

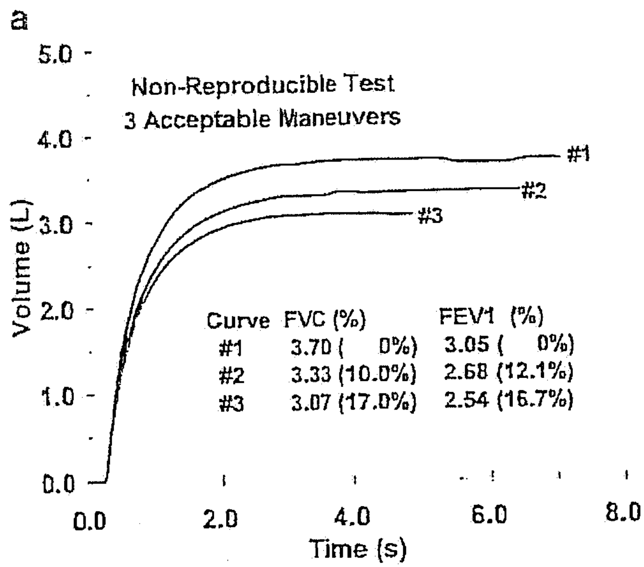


Figure A7a. Nonreproducible test with three acceptable volume–time curves. Percents are difference from largest value.

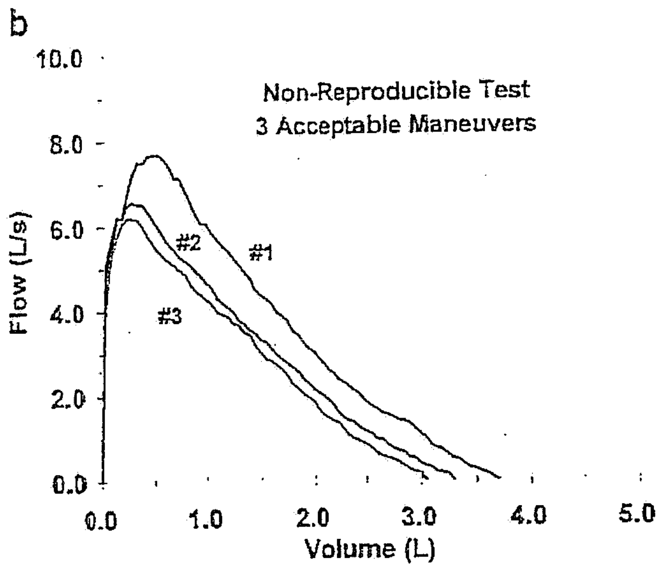


Figure A7b. Nonreproducible test with three acceptable flow–volume curves.

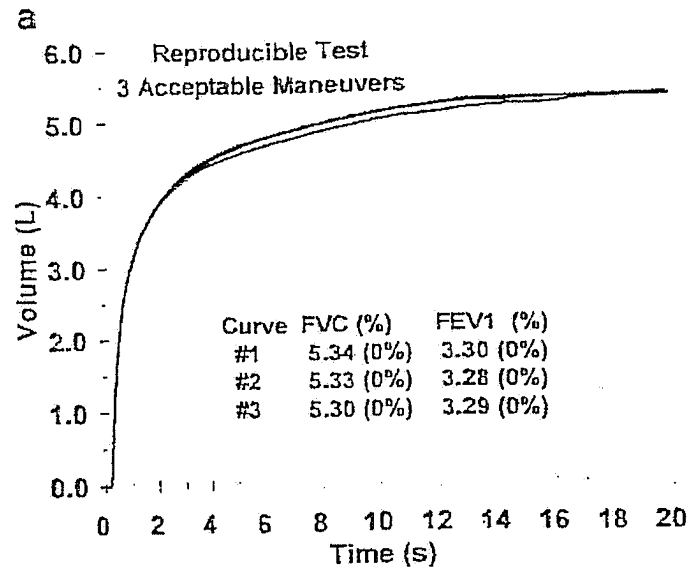


Figure A8a. Reproducible test with three acceptable volume–time curves. Percents are difference from largest value.

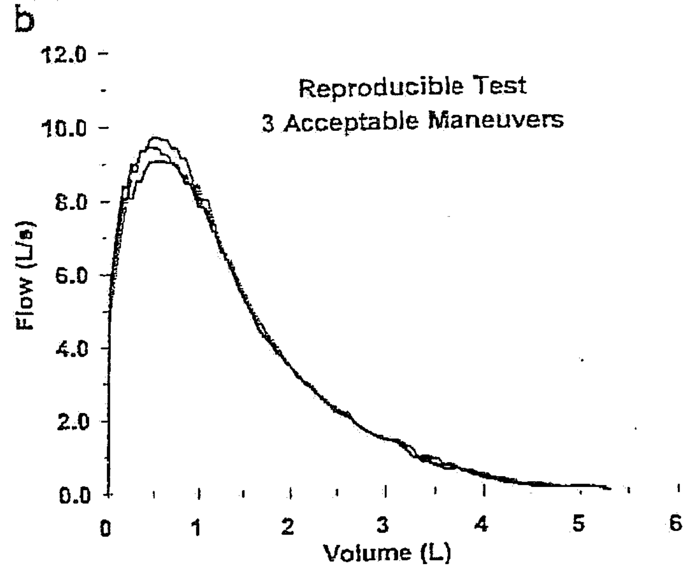


Figure A8b. Reproducible test with three acceptable flow–volume curves.

ing tested should not receive any adjustments or special calibration procedures that are not part of its routine operational procedures.

Volume parameters should be validated using the 24 volume–time standard waveforms described in Appendix C. For PEF and other flow parameters *not* based on a percentage of the FVC, the 26 flow–time standard waveforms should be used (Appendix D). The validation limits are provided for each parameter in the main sections of this statement. All tests should be conducted using the appropriate waveforms and a computer-controlled mechanical syringe or its equivalent (waveform generator). The accuracy of the waveform generator should be checked at least daily when in use, either using a spirometer for volume waveforms or a pneumotachometer for flow waveforms, or an equivalent method. The desired accuracy of the waveform generator for volume parameters is ± 0.5% (or ± 0.05 L, whichever is greater); ± 2% (or ± 5 L/min, whichever is greater) for flow parameters (e.g., PEF). In comparing results obtained from a particular spirometer, the tolerance limits of the waveform generator are to be considered by adding them to the accuracy requirement for the parameter under test, for example 0.5% (± 0.05 L) for volume parameters and 2% (± 5 L/min) for flow parameters. Therefore, the FVC accuracy requirement for comparisons with observed values would be ± 3.5% (performance accuracy requirement ± 3% plus waveform generator accuracy of ± 0.5%).

The accuracy and precision validation limits contained in this section assume a waveform generator accuracy of 0.5% for volume and 2% for flow parameters. The accuracy of available waveform generators has not been established; therefore, the desired 2% waveform generator accuracy for flow parameters may not be achieved. In this circumstance, the *actual* accuracy limit of the waveform generator should be added to the accuracy require-

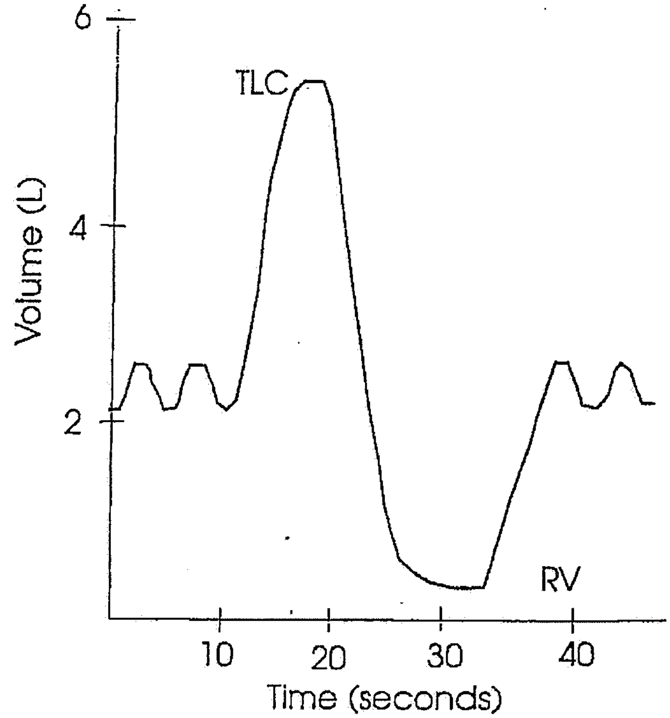


Figure A9. Sample relaxed VC maneuver in a normal subject.

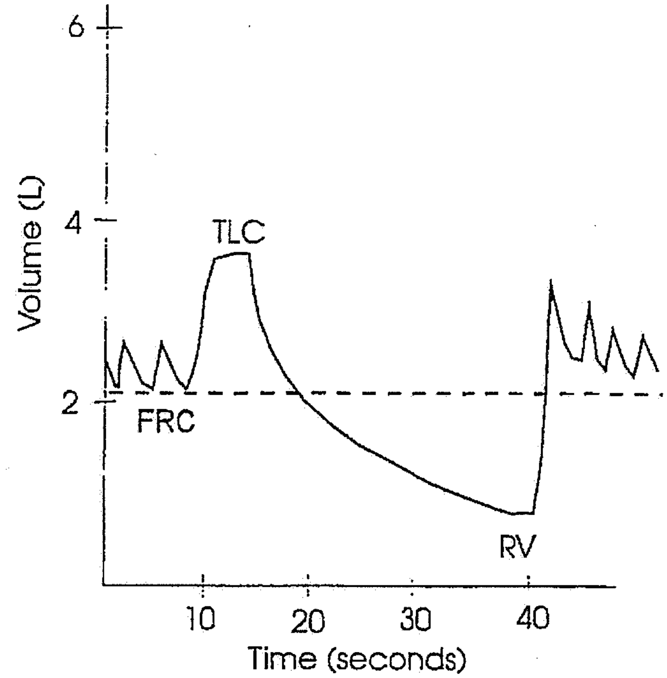


Figure A10. Sample VC maneuver from a subject with severe airways obstruction.

ment of the parameter under test. Every attempt should be made to improve the accuracy of waveform simulators, but in no case should the simulator accuracy limit be considered less than 0.5% for volume and 2% for flow parameters.

Spirometers or peak flow meters should be connected to the waveform generator in the same orientation used in the testing of subjects. Tubing or other connecting material may be used, but the volume associated with the connecting tubing should be less than 300 ml. For handheld devices, full testing should be conducted with the sensor in a horizontal position (the typical position with the patient at TLC about to initiate the maneuver). In addition, handheld devices should be tested with two waveforms (standard volume–time waveforms 1 and 6) at a typical FRC position (instrument at a 30° angle down from horizontal). These devices must meet diagnostic spirometer accuracy criteria for these two waveforms in the 30° down-angle position.

The instruments (diagnostic or monitoring devices) should be tested using the waveform generator under conditions similar to those present when testing human subjects. No special procedures should be followed in testing the instrument. Specifically, each waveform will be injected into the instrument within not less than 5 s or more than 1 min of the instrument being set to the ready condition. In measuring the resistance of the instrument, pressure should be measured in the side of the standard mouthpiece used by the instrument when constant flows are injected into the spirometer. If an in-line filter is to be used as part of routine testing of humans, a filter must be attached during spirometer validation and resistance testing.

Five repeats of each of the 24 waveforms should be injected into the test instrument using room air at ambient temperature. In those circumstances where the flow or volume sensor is changed between subjects (e.g., disposable flow sensor), a different sensor should be used for each of the repeat tests. The average of the five repeat values should be used for comparison with the standard values. The range and percent deviations of values from the five repeated tests should also be computed by:

$$\text{Range} = \text{maximum} - \text{minimum} \qquad \text{(B1)}$$

$$\text{Range (\%)} = 100 * \frac{(\text{maximum} - \text{minimum})}{\text{average}} \qquad \text{(B2)}$$

$$\text{Deviation} = \text{average} - \text{standard} \qquad \text{(B3)}$$

$$\text{Deviation (\%)} = 100 * \frac{(\text{average} - \text{standard})}{\text{standard}} \qquad \text{(B4)}$$

Averages are calculated as a simple n weighted average.

The five repeats of 24 waveforms should be considered a rigid testing sequence. The testing of a device should be completed by running all 24 waveforms with five repeated tests. If the device fails to accurately measure a value for a particular waveform, no additional repeats should be conducted for only one waveform.

Diagnostic devices should also be tested by injecting at least four waveforms using heated and humidified air (waveforms 1 through 4) to verify accuracy of volume parameters under BTPS conditions. Using volume–time waveforms 1 through 4, the average FVC and FEV_1 of three trials shall be compared to the standard values. The validation limits for testing under BTPS conditions are ± 4.5% or 200 ml, whichever is greater. Spirometers must meet these accuracy criteria for all four waveforms under BTPS conditions. Using 4.5% allows a 1.5% simulator error, necessary because of the added uncertainty when using heated and humidified air. The time between each of the three trials should be less than 2 min. The temperature of the air injected into the device under test should be within ± 1° C of 37° C and should be measured before the air is injected into the device. Waveform generators are being modified to allow BTPS testing. The BTPS testing requirement will be implemented when BTPS testing services are available.

In addition to testing using the waveform generator, the device should be tested using at least two healthy human subjects.

TABLE B1

STROKE VOLUME, VOLUME IN SPIROMETER AT START OF TEST (FOR VOLUME SPIROMETERS), RATE, AND CORRESPONDING MVV TARGET VALUES

Test Number	Target MVV (L/min)	Stroke Volume (L)	Rate (Strokes/min)	Starting Volume (L)
1	60	1.0	60	2.0
2	100	1.0	100	3.0
3	120	2.0	60	3.0
4	200	2.0	100	3.0

The purpose of the testing using a human subject is to verify that the instrument will function properly under conditions other than those present using a mechanical simulator. To achieve a balanced design, each subject should perform alternating maneuvers between a standard spirometer and the device being tested, performing three maneuvers on each device, for a total of six maneuvers. One subject should be randomly assigned to perform their first maneuver on the standard spirometer while the other subject's first maneuver will be performed on the device being tested, allowing the learning effect to be equally distributed across both instruments. The differences between the largest of the three trials from each device should be within ± 6% or 200 ml, whichever is greater, for FVC and FEV_1, and ± 15% or 30 L/min, whichever is greater, for PEF.

For validating MVV, a mechanical pump should be used with a sinusoidal waveform. The response of the device should be determined using incrementally increased flows up to a maximum of 250 L/min, produced with stroke volumes up to 2 L. The specific minimum patterns and for volume spirometers, the volume in the spirometer, are given in Table B1. The device should read the MVV within ± 10.5% of reading or ± 20 L/min, whichever is greater for all four test patterns specified in Table B1. In addition, the pressure measured at the mouthpiece should not exceed 10 cm H_2O during the entire MVV maneuver. No mechanical pump testing at BTPS is required for MVV.

DIAGNOSTIC DEVICES: TESTING FOR ACCURACY AND PRECISION WITH A WAVEFORM GENERATOR

Accuracy Testing

Accuracy criteria: Deviation ± 3.5% or ± 0.100 L, whichever is greater, for volume measurements; ± 5.5% or ± 0.250 L/s, whichever is greater, for $FEF_{25-75\%}$; ± 12% or ± 25 L/min (± 0.420 L/s), whichever is greater, for PEF. These criteria are increased slightly from those in Table 2 to account for the waveform generator inaccuracy. For MVV testing, deviation must be less than ± 10.5% or 20 L/min, whichever is greater.

Waveforms: Twenty-four standard volume–time waveforms (APPENDIX C) for FVC, FEV_1, and $FEF_{25-75\%}$; 26 standard flow–time waveforms (APPENDIX D) for PEF. For BTPS testing, volume-time waveforms 1 through 4 should be used with heated and humidified air as specified in this appendix. For MVV testing, sinusoidal waveforms should be used with the patterns specified in Table B1.

Spirometer tested: One production spirometer. Spirometers should not be screened or especially calibrated before testing. If an in-line filter is to be used during the testing of humans, it should be attached for this testing. When during clinical testing, if the flow or volume sensor is changed between subjects, the sensors must be changed for each of the five repeat tests described below. The spirometer may not be recalibrated after these sensor changes unless recalibration is required after each sensor change during clinical testing.

Validation: Each spirometric waveform is to be injected into the spirometer five times. MVV patterns will be injected in duplicate. Average values will be calculated for each waveform and, along with individual values, will be used to score the spirometer. See formulas B1–B4.

Acceptable performance: For FVC and FEV_1, in each of the volume–time waveforms: deviation (formula B3) must be less than 0.100 L *or* deviation (%) (formula B4) must be less than 3.5%. For $FEF_{25-75\%}$ in each of the volume–time waveforms: deviation must be less than 0.250 L/s *or* deviation (%) must be less than 5.5%. For PEF in each of the flow–time waveforms: deviation must be less than 25 L/min (0.420 L/s) or deviation (%) must be less than 12%. For BTPS testing using waveforms 1–4: deviation must be less than 0.2 L or deviation (%) must be less than 4.5%. For MVV in each of the patterns: deviation must be less than 20 L/min or deviation (%) must be less than 10.5%.

An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. For testing with ambient air, acceptable performance is present if the error rate for each individual parameter (FVC, FEV_1, $FEF_{25-75\%}$, PEF) is less than 5% (one error for each parameter when 24 or 26 waveforms are used). For MVV testing and spirometric testing with BTPS conditions, acceptable performance is present if the error rate is zero.

Precision Testing: Intradevice Testing

Precision criteria: See the acceptable performance criteria listed below.

Waveforms: Use data generated as part of accuracy testing. Acceptable performance: For FVC and FEV_1, for each of the volume–time waveforms: The range (formula B1) must be less than 0.100 L *or* range (%) (formula B2) must be less than 3.5%. For $FEF_{25-75\%}$ using each of the volume–time waveforms: The range (formula B1) must be less than 0.250 L/s or the range (%) (formula B2) must be less than 5.5%. For PEF using each of the flow-time waveforms: The range must be less than 25 L/min (0.420 L/s) or the range (%) must be less than 7%.

An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if the error rate for each individual parameter (FVC, FEV_1 PEF) is less than 5% (one error for each parameter if 24 or 26 waveforms are used).

MONITORING DEVICES (PEF) TESTING CRITERIA

The range and deviations from the standard PEF values should be calculated using formulas B1 through B4.

Accuracy Testing

Accuracy criterion: ± 12% or ± 25 L/min of target values, whichever is larger. The primary criterion is ± 10%; 2% is added to account for the inaccuracy of the waveform generator.

Waveforms: 26 flow–time curves (APPENDIX D).

Meters tested: Two production meters. Meters should be selected routinely from a production run and not be screened before validation testing.

Validation: Each meter will receive five maneuvers for each of the 26 waveforms. An average for each waveform will be calculated and used to score that meter against the accuracy criteria.

Acceptable performance: An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. Acceptable performance is less than three errors out of the total 52 tests (26 waveforms, 2 meters).

Precision Testing: Intradevice Testing

Criterion: Less than 6% intradevice variability or 15 L/min, whichever is greater. The primary criterion is less than 5%. One per-

TABLE C1

VALUES FOR STANDARD WAVEFORMS

Curve	FVC (L)	FEV_1 (L)	FEV_1 (%FVC)	Vext (L)	Vext (%FVC)	FEF_{max} (L/s)	$FEV_{25-75\%}$ (L/s)
1	6.000	4.262	71.0	0.052	0.9	6.497	3.410
2	4.999	4.574	91.5	0.068	1.4	9.873	5.683
3	3.498	1.188	33.9	0.014	0.4	1.380	0.644
4	1.498	1.371	91.5	0.019	1.3	2.952	1.704
5	5.132	3.868	75.4	0.087	1.7	7.535	3.209
6	4.011	3.027	75.5	0.317	7.9	5.063	2.572
7	3.169	2.519	79.5	0.354	11.2	4.750	2.368
8	1.993	1.615	81.0	0.151	7.6	3.450	1.857
9	4.854	3.772	77.7	0.203	4.2	7.778	3.365
10	3.843	3.031	78.9	0.244	6.3	4.650	2.899
11	2.735	1.811	66.2	0.022	0.8	3.708	1.272
12	2.002	1.621	81.0	0.094	4.7	3.807	1.780
13	4.896	3.834	78.3	0.460	9.4	5.207	3.677
14	3.786	3.053	80.6	0.338	10.2	4.368	3.122
15	5.937	5.304	89.3	0.080	1.3	12.132	6.092
16	5.458	3.896	71.4	0.215	3.9	7.395	2.892
17	5.833	2.597	44.5	0.035	0.6	5.257	1.153
18	4.343	3.155	72.6	0.042	1.0	7.523	2.335
19	3.935	2.512	63.8	0.044	1.1	5.408	1.137
20	2.881	2.563	89.0	0.041	1.4	5.822	2.695
21	4.477	3.549	79.3	0.102	2.3	9.398	3.368
22	3.857	2.813	72.9	0.036	0.9	5.055	2.204
23	3.419	1.360	39.8	0.013	0.4	2.868	0.531
24	1.237	0.922	74.5	0.037	3.0	2.095	0.709

Definition of abbreviations: Vext = extrapolated volume (*see* Figure 2 for description).

cent or 5 L/min is added to account for the imprecision of the waveform generator.

Waveforms: Four of the 26 standard flow–time waveforms (waveforms 1, 4, 8, and 25).

Meters tested: Ten production meters.

Validation: Three flows for each waveform for each meter. For each waveform and for each meter, calculate range (formula B1) and range (%) (formula B2) for each PEF.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is six or fewer errors (error rate ± 5% for 120 trials).

Precision Testing: Interdevice Variability

Criterion: Less than 11% interdevice variability or 25 L/min, whichever is greater. This includes 1% or 5 L/min for the imprecision of the waveform generator.

Waveforms: Same as for intradevice testing.

Meters tested: Same as for intradevice testing.

Validation: Same data as for intradevice testing. Interdevice percentage is calculated as follows: for each meter, calculate an average PEF for each waveform. For each waveform, combine all data from the 10 meters to calculate range (formula B1) and range (%) (formula B2) for each of the four waveforms.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if there are no errors.

TABLE D1

CALCULATED VALUES FOR 26 STANDARD FLOW–TIME WAVEFORMS (0.002-S SAMPLING INTERVAL)*

Waveform Number	Flow PEF (L/s)	Vol-80 PEF (L/s)	Vol-40 PEF (L/s)	Rise-Time (ms)	Vext Time-to-PEF (ms)	Flow Time-to-PEF (ms)	Extr Vol (L)	%Vext (%FVC)	FEV_1 (L)
1	7.445	7.245	7.337	93.5	86.8	151.7	0.108	2.5	3.373
2	10.860	9.905	10.450	55.7	46.5	86.6	0.093	2.2	3.838
3	4.794	4.372	4.630	68.3	53.0	114.7	0.054	3.3	1.302
4	4.401	4.240	4.321	76.0	65.6	116.3	0.051	2.9	1.468
5	3.630	3.564	3.584	159.5	170.6	241.0	0.081	3.0	2.053
6	3.088	2.728	2.949	44.5	36.8	62.7	0.021	1.3	1.110
7	2.509	2.237	2.403	148.0	67.6	173.6	0.057	3.7	1.046
8	2.328	2.048	2.210	42.4	35.6	57.6	0.015	1.0	0.950
9	5.259	4.923	5.109	57.0	47.2	85.4	0.046	1.8	2.182
10	4.733	4.657	4.666	46.7	93.6	122.2	0.035	1.5	2.029
11	6.870	6.472	6.706	81.1	67.4	125.6	0.085	3.1	2.080
12	10.684	10.528	10.558	115.3	139.9	214.1	0.189	3.4	4.618
13	4.804	4.708	4.739	105.3	121.7	194.9	0.080	2.7	2.304
14	3.821	3.756	3.769	124.7	127.7	201.8	0.074	2.5	2.249
15	7.956	7.814	7.852	174.9	152.6	270.4	0.192	5.0	3.219
16	5.251	5.100	5.165	76.3	80.5	123.7	0.060	2.1	2.246
17	5.842	5.721	5.757	165.1	163.4	265.1	0.151	5.0	2.802
18	8.593	8.404	8.465	132.9	126.2	248.7	0.178	3.6	4.303
19	6.953	6.651	6.807	76.5	63.7	120.2	0.083	2.2	3.007
20	7.430	7.274	7.324	120.9	143.3	268.4	0.141	2.5	4.613
21	3.973	3.745	3.880	130.3	88.4	193.1	0.079	6.0	1.096
22	3.377	3.316	3.334	184.2	157.6	259.6	0.094	5.0	1.559
23	8.132	7.954	8.019	84.8	83.1	152.1	0.107	2.4	3.476
24	4.155	4.028	4.086	50.3	52.3	83.7	0.032	1.2	1.833
25	14.194	13.896	13.964	57.9	53.7	100.3	0.126	1.9	5.944
26	11.595	10.446	11.172	49.6	42.2	79.1	0.088	1.7	4.311

Definition of abbreviations: Flow PEF = peak flow determined by obtained highest observed flow value; Vol-80 PEF = peak flow determined from volume–time curve using an 80-ms segment; Vol-40 PEF = Peak flow determined from volume–time curve using a 40-ms segment; Rise-Time = time required for the flow to rise from 10% of PEF to 90% of PEF; Flow Time-to-PEF = time required for flow to rise from 200 ml/s to maximum flow (PEF); Vext Time-to-PEF = time required for flow to rise from Vext time zero to PEF.

* Units: flow (L/s), volumes (L), and time (milliseconds). These waveforms are available on digital media from the American Thoracic Society.

MONITORING DEVICES (FVC AND FEV_1) TESTING CRITERIA

Accuracy Testing

Criterion: Deviation ± 5.5% *or* deviation (%) ± 0.1 L, whichever is larger.

Waveforms: Twenty-four standard volume–time waveforms (APPENDIX C).

Device testing: Two production devices selected routinely from a production run and not screened before testing.

Validation: Each device will receive five maneuvers for each of the 24 waveforms. An average for each waveform will be calculated and used to score that meter against the accuracy criteria.

Acceptable performance: An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. Acceptable performance for each individual parameter is less than three errors out of the total 48 tests (24 waveforms, 2 devices).

Precision Testing: Intradevice Testing

Criterion: Range (%) < 3.5% or range < 0.1 L, whichever is greater.

Waveforms: Four of the 24 standard volume–time waveforms (waveforms 1, 3, 6, and 11).

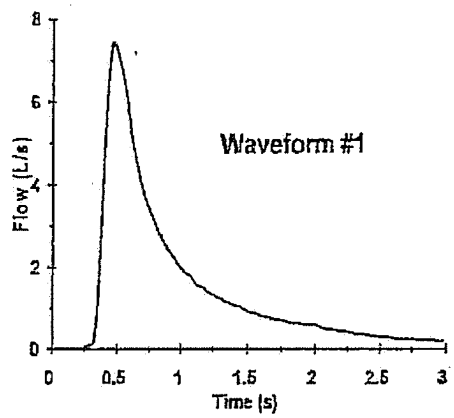
Meters tested: Ten production devices.

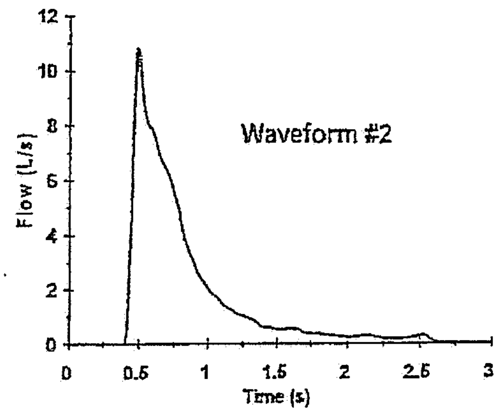
Validation: Three flows for each waveform for each device. For each waveform and for each device, calculate range (formula B1) and range (%) (formula B2) for FVC and FEV_1.

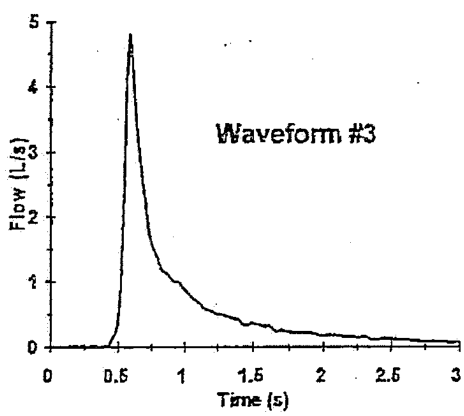
Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance for each individual parameter is six or fewer errors (error rate ± 5% for 120 trials).

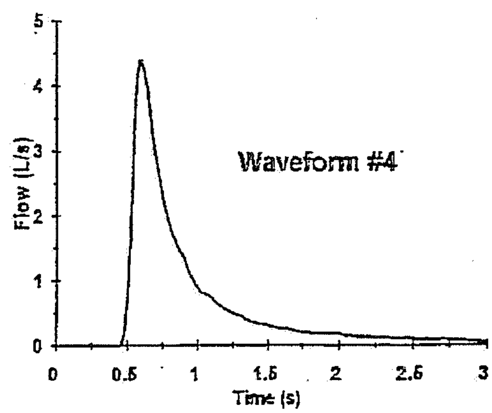
Precision Testing: Interdevice Variability

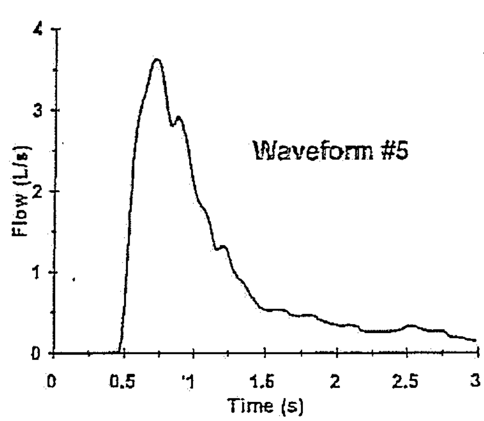
Criterion: Less than 11% interdevice variability or 0.2 L, whichever is greater.

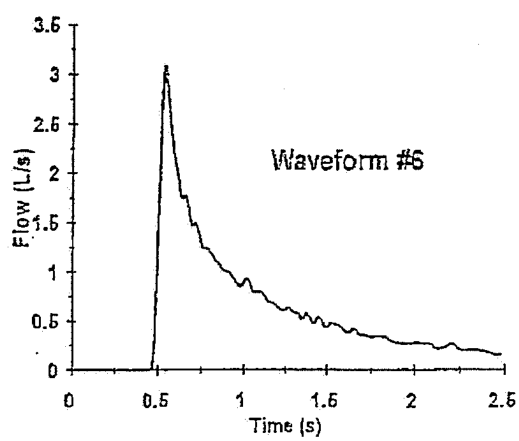


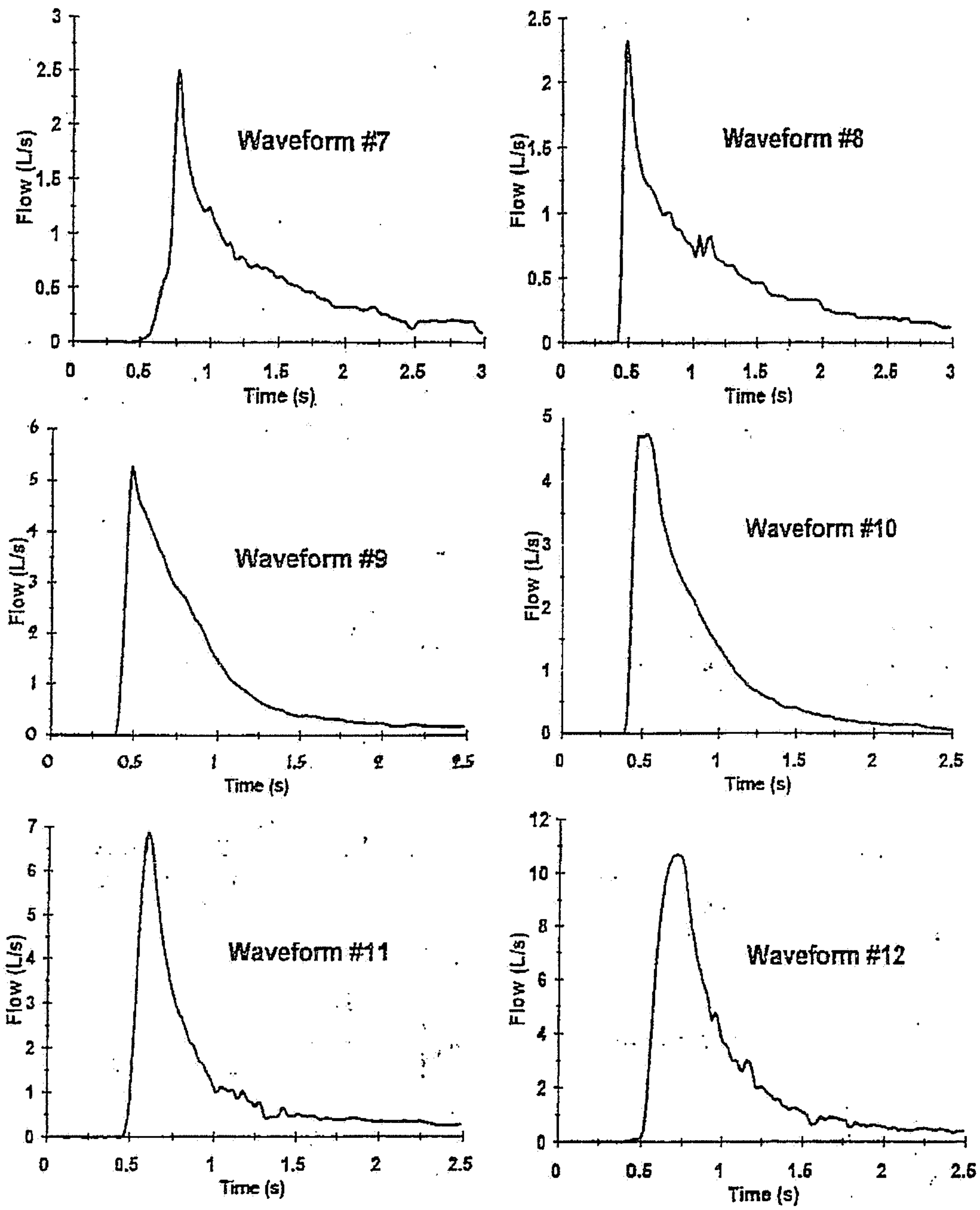












Waveforms: Same as for intradevice testing.

Devices tested: Same as for intradevice testing.

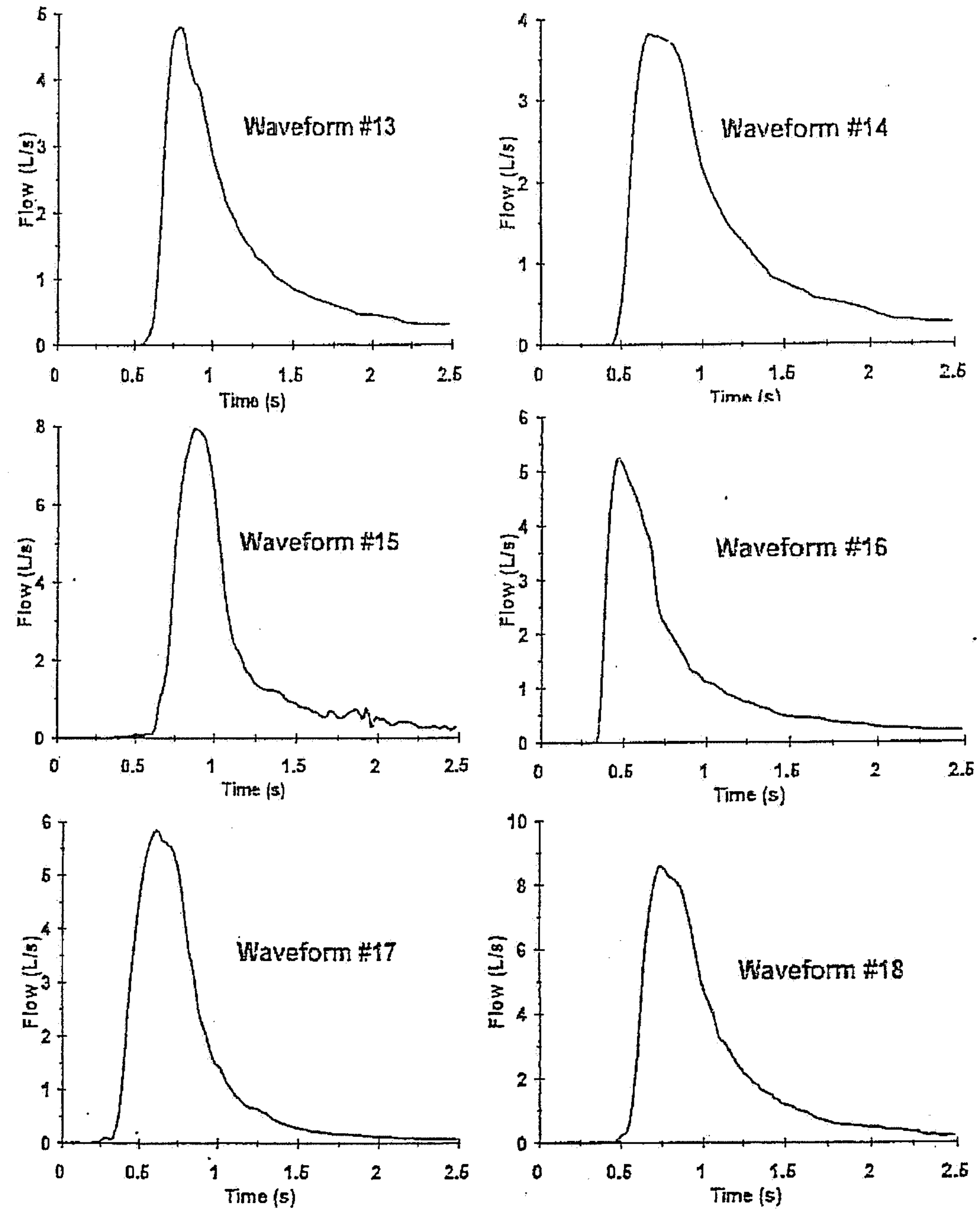
Validation: Same data as for intradevice testing. Interdevice percentage is calculated as follows: for each device, calculate an average FVC and FEV_1 for each waveform. For each waveform and parameter, combine all data from 10 meters to calculate range (formula B1) and range (%) (formula B2) for each of the four waveforms.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if there are no errors.

APPENDIX D

Standard Flow–Time Waveforms for Validating PEF

The following flow–time waveforms are intended primarily for testing portable PEF meters but can be used for testing other types of spirometers, especially those measuring PEF, time-to-peak flow, or rise-time. These waveforms were chosen to represent a range of PEFs and efforts (rise-times). The PEF is derived directly from the flow–time waveform–maximal observed value. To calculate the volume-determined PEF, volume is first obtained by integrating (summing) the flow values. Flow is then calculated from the volume–time waveform using the ATS 8-point smoothing function. The resulting volume PEF is usually lower than the PEF obtained from the flow–time waveform. Rise-time is defined as the time required for the flow to rise from 10% of the PEF to 90% of the PEF and is expressed in milliseconds. Other investigators have used the time-to-PEF, using the back-extrapolated technique to determine the zero time-point. Using back-extrapolation to calculate time-to-peak flow sometimes



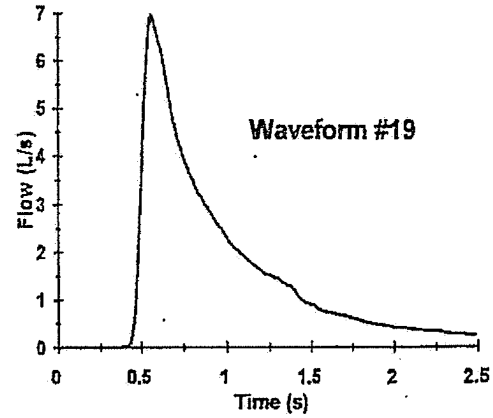
results in artificially lower time-to-PEF, as can be seen in waveform 7.

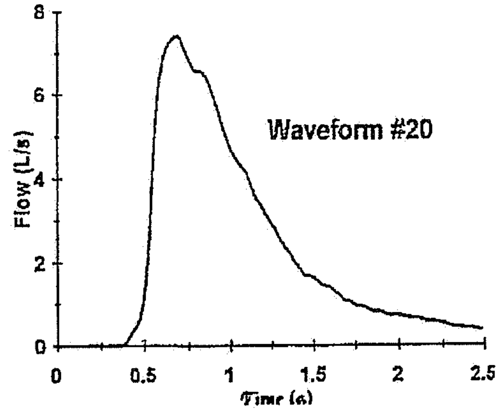
APPENDIX E

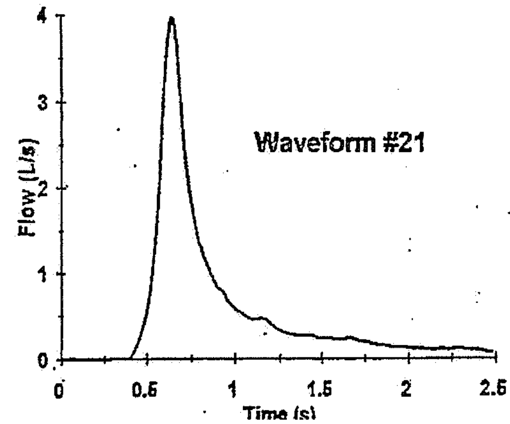
Signal-Processing Tutorial

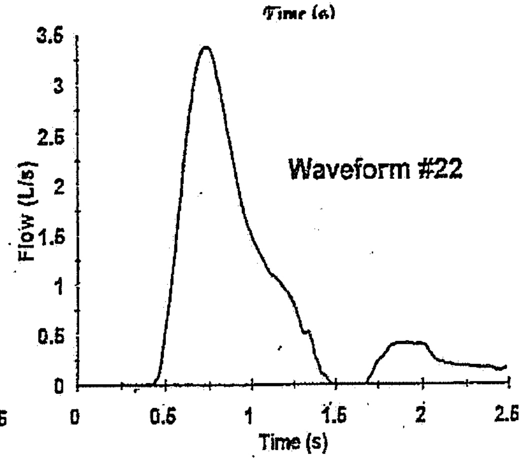
Since computers have come into such common use in spirometry and since fundamental errors have been detected in recently tested commercially available hardware and software (79), a short tutorial on signal processing is presented (Figure E1).

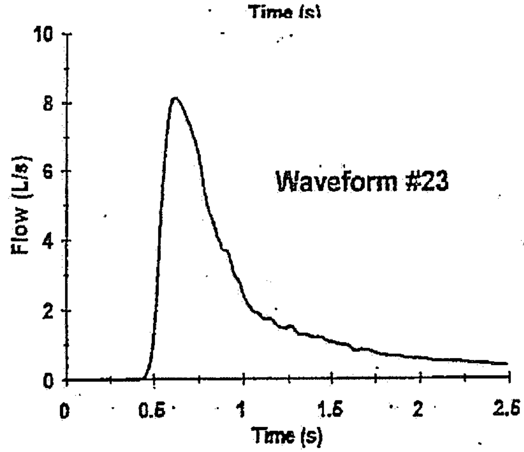
For volume spirometers, signals are generally derived from electrical voltages from a potentiometer. Some spirometers also use optical shaft or position encoders (80). Flow devices of the Fleisch pneumotachometer variety also have electrical voltage outputs. For the volume spirometer with a potentiometer and the flow device with a flow transducer, the signal is sampled by a computer's analog to digital (A-to-D) converter. The ability of these systems to accurately measure the spirogram depends on the volume or flow transducer's linearity, the accuracy and linearity of the electrical transducer (potentiometer), and the resolution of the A-to-D converter. A resolution of 12 bits (1 part in 4,096, raw resolution from 0.003 to 0.004 L) for the A-to-D converter is recommended, although 10 bits (1 part in 1,024, raw resolution from 0.008 to 0.016 L) may be adequate for sampling volume. The sampling rate of the spirometer volume or flow is very important. Lemen and associates (19) have shown

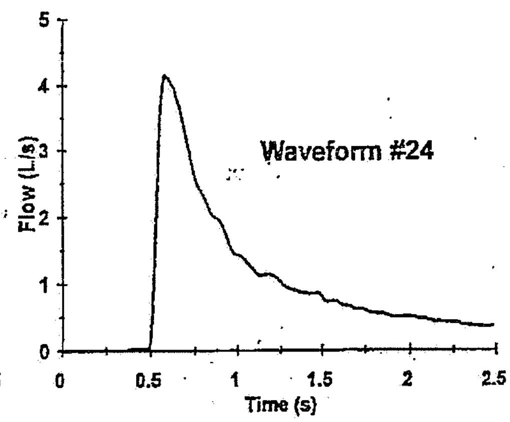

Waveform #19
Flow (L/s)
Time (s)

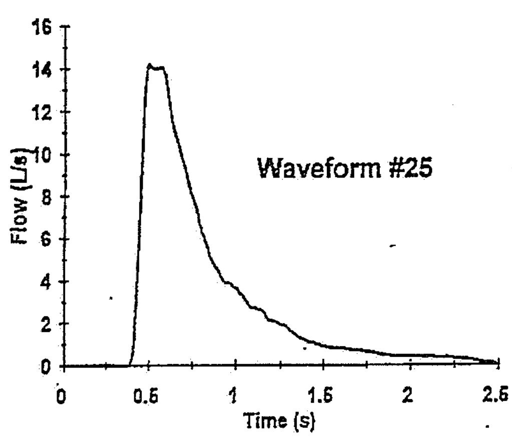

Waveform #20
Flow (L/s)

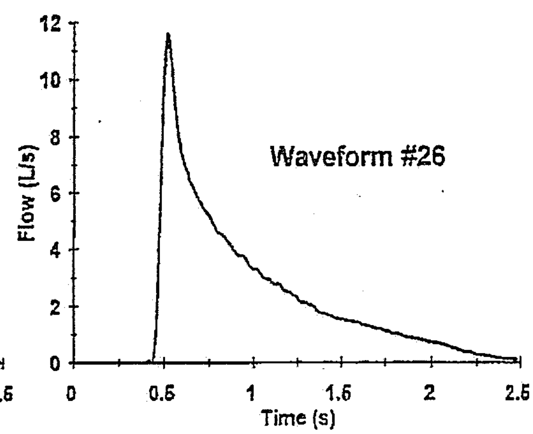

Waveform #21
Flow (L/s)


Waveform #22
Flow (L/s)
Time (s)


Waveform #23
Flow (L/s)
Time (s)


Waveform #24
Flow (L/s)
Time (s)


Waveform #25
Flow (L/s)
Time (s)


Waveform #26
Flow (L/s)
Time (s)

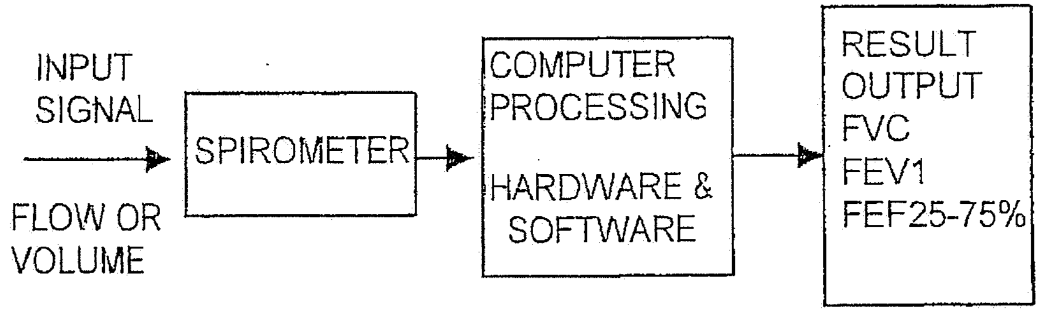


Figure E1. Block diagram of spirometer data acquisition.

that for both infants and adults, 95% of the signal energy in the flow-time spirogram is within a bandwidth of zero to 12 Hz. For the volume-time curve, 95% of the signal energy is contained from zero to 6 Hz. Digital sampling theory requires that samples be taken at least twice the rate of the highest frequency contained in the signal (81). Thus for volume-time spirograms, a 12-Hz sampling rate should be adequate. However, most volume-time spirograms are sampled at a 100-Hz or greater rate to make measurements easier and more accurate. Computer system developers should be aware that even with 100-Hz sampling, it may be necessary to linearly interpolate between sampling points to determine accurate FEV_1, $FEF_{25-75\%}$, and other similar spirometric measures.

Volume sampling techniques with optical and shaft or position encoders of the volume-time signal have been used (80). This approach measures the time interval between uniform volume intervals (for example, 0.010 L). In this case, the resolution of the time interval between measurements during rapid flow becomes a limiting factor. Ostler and associates have recently addressed these issues (80). For example, if a resolution of flow to within $\pm$ 5% of reading at 12 L/s for a system with 0.010-L resolution is required, then a clock resolution of at least 40 μs is needed (80).

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6

'American Thoracic Societv
MEDICAL SECTION OF THE AMERICAN LUNG ASSOCIATION

Guidelines for the Evaluation of Impairment/Disability in Patients with Asthma

BACKGROUND

The 1982 and 1988 American Thoracic Society (ATS) statements (1, 2) on the evaluation of impairment and disability caused by respiratory disorders were primarily of relevance for patients with respiratory diirders associated with irreversible damage. Asthma was dealt with only as a **modifying** condition. Patients with asthma have features that differ from other respiratory disorders, including: (1) The condition is characterized by variable airflow obstruction and the individual's clinical status varies from time to time; (2) the airflow limitation is partially or completely reversible with appropriate therapy; (3) the condition is associated with airway hyperresponsiveness to irritants such as dusts, fumes, gases, or smoke; (4) in many cases, environmental or occupational exposure to specific sensitizers provokes airway inflammation, which, on repeated exposure may become chronic and irreversible. Specific guidelines for patients with asthma are necessary because of these features.

PURPOSE

The purpose of this statement is to provide specific guidelines for the determination of impairment and disabilii in subjects with asthma for use by health professionals and **disability** boards. It takes into consideration not only impairment related to reduced lung function but other parameters, such as the degree of airway hyperresponsiveness and the type and amount of medication required to control symptoms, which are important reflections of the severity of asthma (3). This statement does not address the methods of identification of the cause of asthma.

DEFINITIONS

The definitions used by the previous **ATS** statement (2) will be used here.

Impairment is defined as a functional **abnormality** resulting from a medical condition. It may or may not be stable at the time the evaluation is made, and may be temporary or permanent. Impairment that persists after appropriate therapy, with no prospect of future improvement, is permanent. Some impairments are not de **pendent** on lung function, but are related to the prognosis (e.g., **unresectable** lung cancer) or to public health considerations (e.g., tuberculosis) or inability to work in the same environment that causes asthma (e.g., occupational asthma).

Disability is a term used to indicate the total effect of impairment on the patient's life. It is affected by diverse factors such as age, sex, education, economic and social environment, and the energy requirement of the occupation.

Two people with identical impairmentmaybediirentlyaffectsd in their life situations. The rating of health impairment is within the jurisdiction of a physician's expertise to **quantitate**. However, the determination of dillii also requires consideration of many nonmedical variables. Physicians, however, generally have considerable knowledge about how impairment affects their patients lives. Therefore it is important for physicians to identify all the individual factors modifying the impact of impairment on their patients' lives for administrators who determine disability compensation.

DIAGNOSIS OF ASTHMA

Asthma should be suspected in the presence of a compatible history of cough, sputum, wheeze, chest tightness, or breathlessness, particularly when the symptoms are episodic and worse at night (4). The diagnosis of asthma requires both relevant symptoms (currently or by history) and the presence of airflow limitation that is partially or completely reversible either spontaneously or after treatment, or the presence of airway hyperresponsiveness to methacholine or histamine in the absence of airflow limitation.

In the presence of severe airflow limitation, it may not be possible to distinguish between asthma and other types of obstructive lung disease. Additional diagnostic criteria should be considered such as the presence of blood or sputum eosinophilia.

METHODS

Measurement of Spirometry

Spirometric measurements should be carried out using equip **ment**, methods of calibration, and techniques that meet the criteria outlined in the most recent revision (5) of the ATS official statement on standardiiion of spirometry (6), or subsequent revisions of that statement, whichever is most current. The measurement of height, prediction equations, and corrections for racial differences should follow those outlined in the ATS official statement on "Lung Function Testing: Selection of Reference Values and Interpretational Strategies" (7).

Spirometric measurements should be made, if possible, after withholding inhaled bronchodilators for 8 h and long-acting bronchodilators (e.g., long-acting theophylline preparations) for 24 h. However, if it is not possible to withhold bronchodilators for this period of time, they can be used, but the time these medications are taken before the test should be noted. Antiinflammatory preparations such as cromolyn, inhaled or systemic corticosteroid should not be withheld.

FEV_1, FVC, and FEV_1/FVC should be **determined** from spirometry. When airflow limitation is present, i.e., FEV_1/FVC is less than the lower limit of normal, which is defined as the lowest 5% of the reference population (7), spirometry should be repeated after the administration of an inhaled **β-adrenergic agonist**. An improvement in FEV_1 of 12% or greater, with an absolute change of at least 200 ml, from the baseline level, confirms that there is significant reversibility, and together with the appropriate history, the diagnosis of asthma (7). When the improvement in FEV_1 is $< 12\%$, a steroid trial should be given. This can be given as high-dose inhaled steroid (> 800 mcg beclomethasone or equivalent/day) although prednisone 30 to 40 mg for a period of 1 to 2 wk may be required in some patients. An improvement in FEV_1 of 20% with steroid trial also confirms the presence of asthma. When airflow limitation is absent, i.e., FEV_1/FVC is above the lower limit of normal (7), the level of airway responsiveness should be determined.

Measurement of Airway Responsiveness

Measurement of airway responsiveness is needed for the diagnosis of asthma and for impairment rating when the subject has no current objective evidence of airflow limitation. When the base line FEV_1 is below 70% of predicted, response to the inhaled β-adrenergic agonist and not the measurement of airway responsiveness is the appropriate test to establish the diagnosis of asthma (8).

Measurement of airway responsiveness should be made by methacholine or histamine inhalation test using standardized methods (9-11). It is imperative that standardized methods be used in order to adequately interpret the results. The test should be done after withholding inhaled short-acting β-adrenergic agonist or ipratropium for 6 h and long-acting β-adrenergic agonist or theophylline for 24 h; in the case of histamine tests, short-acting antihistamines should be withheld for 48 h and astemizole for 1 or 2 months. Antiinflammatory preparations should not be withheld because withdrawal of these for a few hours does not influence measurement of airway responsiveness to histamine or methacholine, whereas prolonged withdrawal of these drugs can lead to an exacerbation of asthma. The subjects should be asked to refrain from smoking and exposure to cold air for two hours before the test.

The results should be expressed as the provocation concentration to cause a fall in FEV_1 of 20% (PC_{20} or PD_{20}) (9). Airway hyperresponsiveness is considered to be present when the PC_{20}

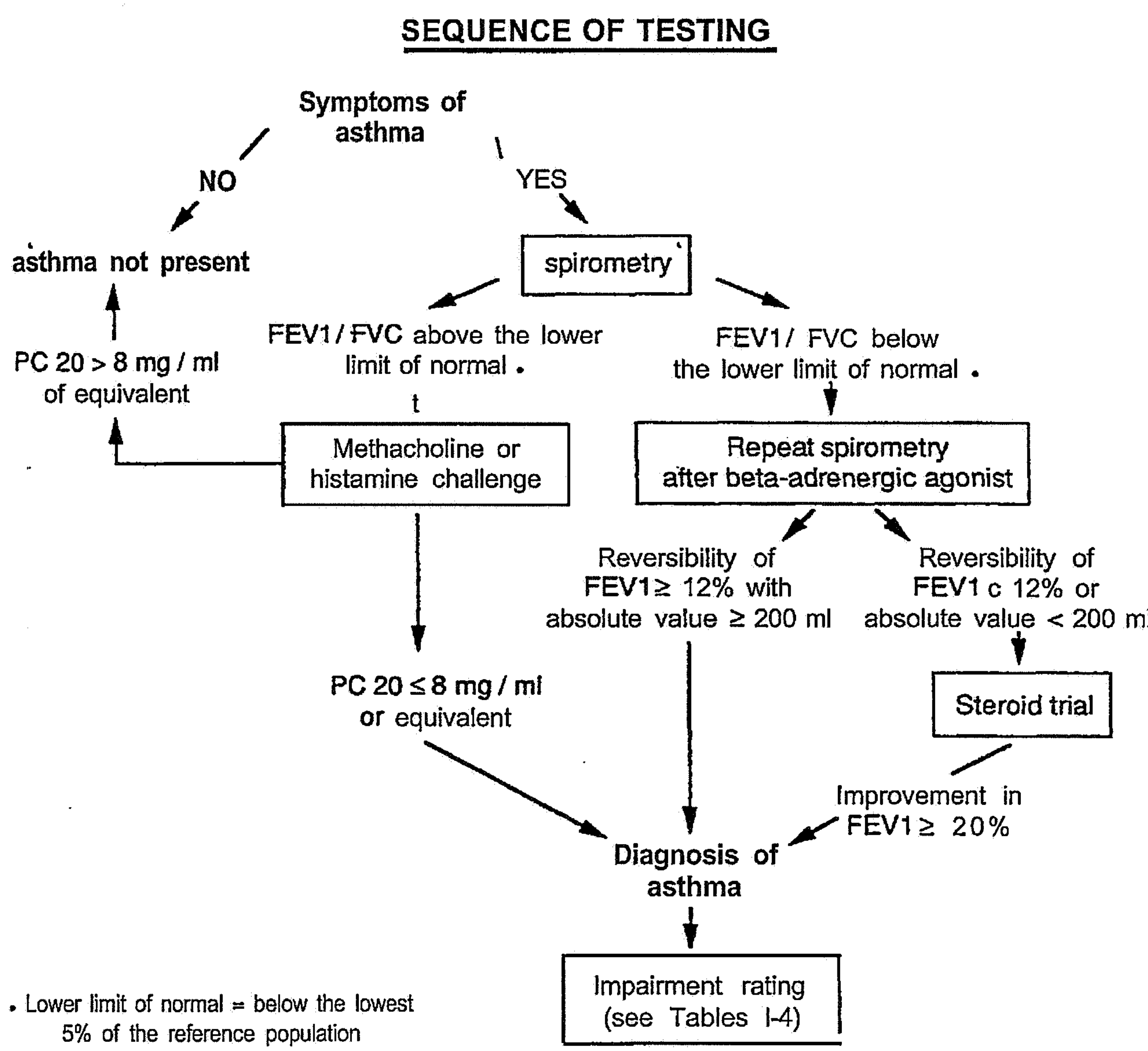

Figure 1. Sequence of testing.

is ≤ 8 mg/ml methacholine or histamine using the tidal breathing method or its equivalent when other standard methods are used (W-12).

Exercise Test

Exercise testing should not be done routinely in the investigation of asthma. However, many physicians perform spirometry before and after exercise testing in the investigation of dyspnea. If a subject has been shown to have a 15% or more decline in FEV_1 from the baseline level after exercise, this information will be useful in the assessment of impairment, particularly if the level of effort is similar to their usual work or daily activities.

Measurement of Diffusing Capacity and Lung Volumes

These measurements are necessary only to distinguish asthma from other conditions. They are not required for impairment evaluation in patients with asthma.

PROCESS OF EVALUATION

The sequence of testing to be performed is defined in figure 1, while figure 2 shows the process of evaluation. There are two types of impairment/disability, temporary and permanent. Temporary impairment/disability refers to a situation that is likely to change. For example, the individual may be expected to improve so that the

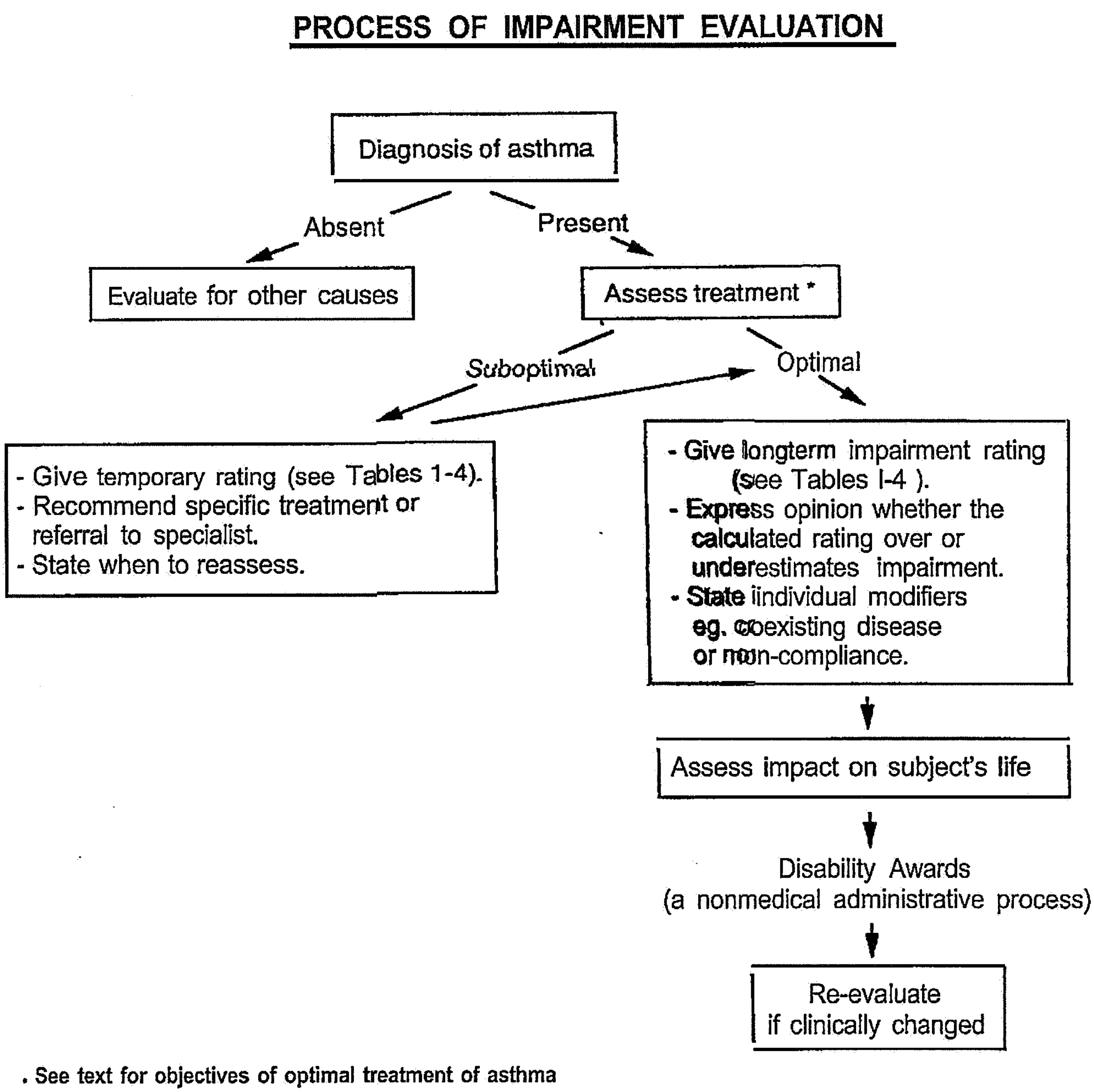

Figure 2. Process of impairment evaluation.

current functional status does not describe the anticipated future status. Temporary impairment/disability can be evaluated from the results of tests used to establish the diagnosis of asthma. Permanent impairment/disability refers to asituation when the individual has reached maximal medical improvement and is receiving op timal therapy. Evaluation for permanent impairment/disability should be done after the objectives of optimal treatment of asthma have been attained.

The objectives of treatment include the following (4):

1. To achieve control or the best overall results (least symptoms, least need for β-adrenergic agonist when taken only if required, best expiratory flow rates, least diurnal variation of flow rates and least side-effects from medication).
2. To use the minimum medication to maintain control or the best overall results.
3. To treat exacerbations early to prevent them from becoming severe.

Physicians involved in the evaluation of impairment should assess whether the objectives of treatment of asthma have been achieved. They should therefore be familiar with the recent published guidelines for treatment of asthma by the National Asthma Expert Panel in the United States (4). In addition to the American Expert Panel's guidelines, other countries such as the United King dom (13), Australia (14), New Zealand (14), and Canada (15) have their own published guidelines. Effective management of asthma depends on both pharmacologic and nonpharmacologic measures. Nonpharmacologic measures include environmental control, patient and family education, and regular supervision. In some subjects it may take several months to achieve the objectives of treatment.

If the objectives of treatment are not achieved, the following should be done:

1. Give rating for temporary impairment (see tables 1 through 4).
2. Recommend specific treatment, or give referral to a specialist experienced in the management of asthma (e.g., pulmonary physician or allergist).
3. State when to reevaluate (when the objectives of treatment have been achieved or in 6 months, whichever is shorter).

RE-EVALUATION

Because asthma may improve or worsen with time, it is necessary to m-evaluate the subject if the clinical status changes even after long-term impairment/disability evaluation has been completed.

PARAMETERS TO BE CONSIDERED FOR RATING OF IMPAIRMENT

Tables 1 through 4 include the parameters used for classifying the extent of impairment. This is done based on both physiologic and clinical parameters.

TABLE 1

POSTBRONCHODILATOR FEV_1

Score	FEV_1 % predicted
0	> lower limit of normal
1	70–lower limit of normal
2	60–69
3	50–59
4	< 50

TABLE 2

REVERSIBILITY OF FEV_1 OR DEGREE OF AIRWAY HYPERRESPONSIVENESS*

Score	% FEV_1 change	or	PC_{20} mg/ml or equivalent
0	< 10		> 8
1	lo-19		8–> 0.5
2	20–29		0.5– > 0.125
3	≥ 30		≤ 0.125
4			

* When FEV_1 is above the lower limit of normal, PC_{20} should be determined and used for rating of impairment: when FEV_1 is < 70% predicted, the degree of reversibility should be used; when FEV_1 is between 70% predicted and the lower limit of normal either reversibility or PC_{20} can be used.

Reversibility with bronchodilator is calculated as.

$$\frac{FEV_1 \text{ post-bronchodilator} - FEV_1 \text{ pre-bronchodilator}}{FEV_1 \text{ pre-bronchodilator}} \times 100\%$$

Airway responsiveness is expressed as that concentration of agent that will provoke a fall in FEV_1 of 20% from the lowest post saline value. Plot the concentration of methacholine/histamine against the fall in FEV_1 using a logarithm scale for the doubling concentrations. The PC_{20} is obtained by interpolation between the last two points. The formula for linear interpolation of the PC_{20} from the log dose response curve is as follows:

$$PC_{20} = \text{antilog } C1 + \frac{(\log C2 - \log C1)(20 - R1)}{(R2 - R1)}$$

Where C1 = second last concentration (< 20% FEV_1 fall)
C2 = last concentraion (> 20% FEV_1 fall)
R1 = % fall FEV_1 after C1
R2 = % fall FEV_1 after C2

Physiologic Parameters

The level of airflow limitation and either its reversibility or the level of airway responsiveness should be used in the impairment rating as shown in tables 1 through 4.

The postbronchodilator FEV_1 should be used in determining the level of airflow limitation. When there is no evidence of airflow limitation as defined above, the score is zero; when there is a severe degree of airflow limitation (FEV_1 < 50% predicted), the score is 4.

Whether the reversibility of airflow limitation or the degree of airway hyperresponsiveness should be used in impairment rating is dependent on the prebronchodilator FEV_1. When the prebronchodilator FEV_1 is above the lower limit of normal, the degree of airway hyperresponsiveness should be used; when the prebronchodilator FEV_1 is between 70% predicted and the lower limit of normal, either the degree of airway hyperresponsiveness or the degree of reversibility can be used; when the prebronchodilator FEV_1 is < 76% predicted, the degree of reversibili should be used.

TABLE 3

MINIMUM MEDICATION NEED*

Score	Medication
0	No medication
1	Occasional bronchodilator, not daily and/or occasional cromolyn, not daily
2	Daily bronchodilator and/or daily cromolyn and/or daily low-dose inhaled sterlcd (< 800 μg beclomethasone or equivalent)
3	Bronchodilator on demand and daily high-dose inhaled steriod (> 800 μg beclomethasone or equivalent) or occasional course (1–3/yr) systemic steroid
4	Bronchodilator on demand and daily high-dose inhaled steriod (> 1000 μg beclomethasone or equivalent) and daily systemic steroid

* The need for minimum medication should be demonstrated by the treating physician. e.g., previous records of exacerbation when medications have been reduced.

TABLE 4
SUMMARY IMPAIRMENT RATING CLASSES.

Impairment Class	Total Score
0	0
I	1-3
II	4-6
III	7-9
IV	10-11
V	Asthma not controlled despite maximal treatment: i.e. FEV, remaining < 50% despite use of ≥ 20 mg prednisone/day.

* The impairment rating is calculated as the sum of the patient's scores from tables 1, 2, and 3.

The degree of reversibility and airway hyperresponsiveness are given less weight compared with the other parameters, with a maximum score of 3.

Clinical Parameters

Although symptoms are a critical component of asthma because of their subjective nature, they should not be the only criterion for impairment rating. The frequency of acute exacerbations requiring emergency room treatment or hospitalization has been used in previous attempts to rate impairment (2). Given the efficacy of currently recommended antiinflammatory preparations in the treatment of asthma, frequent emergency room visits or hospitalizations generally reflect inadequate treatment and failure to achieve the objectives of treatment. The nature and frequency of medications required to maintain asthma under control (or the best results) give a better reflection of the severity of the disease and are more useful for the purpose of impairment assessment. The use of medication requirement as an important component in the rating scheme will be enhanced if the treating physicians follow published treatment guidelines (12-15).

The minimum medication required to maintain control of asthma (or the best results) can be used to rate severity (16), as indicated in table 3. A subject requiring occasional use (not daily) of bronchcdilator (inhaled β-adrenergic agonist or oral theophytline) and/or cromolyn can be considered to have very mild asthma (or a severity score of 1). The need for inhaled β-adrenergic agonist or oral theophyiline on a daily basis and additional daily low-dose inhaled steroid or cromolyn reflects an increase in severity of asthma. The need for daily high-dose inhaled steroid (> 600 mcg of beclomethasone or equivalent doses of other agents) and systemic steroid is given the highest severity score of 4. It is important that the rating physician be confident that these medications are the minimum required to maintain control (or the best results) in a subject and that reduction in medications leads to exacerbation of symp toms and reduced lung function.

IMPAIRMENT RATING

Impairment rating can be determined using the scheme shown in tables 1 through 4. This rating scheme attempts to standardize a method to quantify the effect of the illness on the subjects life, similar to earlier ATS guidelines on evaluation of impairment/disability (1, 2), rather than to quantify the severity of the disease itself. For the description of the clinical disease severity per se, the clinical severity scale of the National Asthma Expert Panel (4) should be used. The degree of impairment is calculated as the sum of the scores for postbronchodilator FEV, reversibility of FEV, or PC_{20}, and medication need. The class of impairment is expressed as Class 0, I, II, III, IV or V. Total impairment/disability (Class V) in a subject with asthma is defined as asthma that cannot be controlled adequately; despite maximal treatment, including ≥ 20 mg oral prednisone per day, the FEV, remains below 50% of predicted.

The evaluating physician may also express an opinion as to whether the impairment rating obtained overestimates or underestimates impairment due to unusual circumstances of individual subjects. These circumstances should be described in detail. Individual modifying factors, such as barriers to compliance in treatment, limitations to environmental control measures, and coexisting disease that might influence the impact of asthma on the subjects life should be clearly stated. In addition, the evaluating physician should indicate the effects asthma has on the subject's quality of life, including the impact on the subject's ability to perform his or her normal job.

SPECIAL CONSIDERATIONS FOR SUBJECTS WITH OCCUPATIONAL ASTHMA

General Comments

Occupational asthma is a disease characterized by variable airflow limitation and/or airway hyperresponsiveness due to causes or conditions that are attributable to a particular occupational environment and not to stimuli encountered outside the workplace. Occupational asthma may encompass both immunologic and nonimmunologic causes: (7) immunologic occupational asthma occurs upon reexposure to an agent after a latent period of immune sensitization; (2) nonimmunologic occupational asthma that does not induce immune sensitization as determined by currently available technology. An irritant and potentially toxic agent may trigger new asthma as an aftermath of an acute inhalation injury in some patients. Such individuals have nonspecific airway hyperresponsiveness and should be evaluated for impairment as for other general forms of asthma.

There are many follow-up studies of subjects with documented occupational asthma showing that the majority (60 to 90%) of sub jects failed to recover several years after leaving exposure (17). Early diagnosis and cessation of exposure are documented prognostic factors that increase the likelihood of a favorable outcome (17). It has been shown that continuous exposure to the offending agent leads to deterioration of symptoms and even fatalities (17). It is therefore important to diagnose occupational asthma early and for the worker to avoid further exposure to the offending agent.

General Approach

Assessment of individuals with occupational asthma should be done by physicians with expertise in this area. Assessment for impairment/disability should take place at least on two occasions.

7. *Temporary impairment/disability.* Once the diagnosis of occupational asthma is made, the proper treatment is to remove the worker from exposure. These patients should be considered 100% impaired on a permanent basis for the job that caused the illness and for other jobs with exposure to the same causative agent. Because the individual cannot return to the previous job,' plans for vocational rehabilitation should be instituted as soon as the diagnosis of occupational asthma is made. It is not necessary to wait for a permanent disability rating to initiate vocational planning. Several alternatives should be considered in the management of subjects with occupational asthma:

- Relocation to a new job either in the same plant or in a different plant where there is no exposure.
- Rehabilitation into a new job or early retirement. Financial compensation should be offered in every instance in which there

is loss of earnings. The amount and duration of compensation should be made known to the worker so that the worker can make rational decisions about the changes.

- In some special situations, modification of the job such as improved ventilation, process change, or product substitution may enable the worker to remain. It is important to remember that when the agent acts by sensitization, the worker may react to levels of exposure well below those considered safe for individuals without prior sensitization. The ability of a respirator to provide adequate protection against the low levels that might trigger an attack and the ability of the asthmatic individual to work safely and effectively with the respirator must be carefully assessed before relying on these devices.

2. *Long-term impairment/disability.* Assessment for long-term impairment/disability should be carried out 2 yr after the removal from exposure when improvement has been shown to plateau (18). Evaluation should be done after the above objectives of treatment have been achieved and using the scaling system as for subjects with nonoccupational asthma.

List *of participants*: This statement was prepared by the ATS Ad Hoc Committee on Impairment/Disability Evaluation in Subjects with Asthma. The members of the Committee are as follows: Moira Chan-Yeung, M.B., (Chair); Philip Harber, M.D.. (Co-Chair); William Bailey, M.D.; John Balmes, M.D.; Scott Barnhart, M.D.; Frederick E. Hargreave, M.D.; Jean-Luc Malo, M.D.; Charles Reed, M.D.; and Hal Richerson, M.D.

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American Thoracic Society

MEDICAL SECTION OF THE AMERICAN LUNG ASSOCIATION

LUNG FUNCTION TESTING: SELECTION OF REFERENCE VALUES AND INTERPRETATIVE STRATEGIES

THIS OFFICIAL STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS ADOPTED BY THE ATS BOARD OF DIRECTORS, MARCH 1991.

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Introduction

Background

During the last 3 decades lung function tests have evolved from tools for physiologic study to clinical tools widely used in assessing respiratory status. In addition to their use in clinical case management, they have become a part of routine health examinations in respiratory, occupational, and sports medicine and in public health screening. It is common practice for the results of lung function tests to be interpreted in relation to reference values, and in terms of whether or not they are considered to be within the "normal" range (1–6). A wide selection of published reference values and "lower limits of normal" is available (4). Computerized equipment adds a new dimension with preselected or menus of reference values and interpretation algorithms whose origin and justification may be unclear.

To maximize the clinical value of lung function tests and to assist those managing clinical lung function testing laboratories, the American Thoracic Society (ATS) (7–12), the European Community for Coal and Steel (ECCS) (4), and the European Society for Clinical Respiratory Physiology (13) have published guidelines, focusing primarily on spirometry as the most widely used lung function test. The 1987 ATS statement in spirometry (8) outlined the steps necessary to achieve standardization: (*1*) equipment performance, validation, and quality control; (*2*) subject performance; (*3*) measurement procedures to determine acceptability and reproducibility; (*4*) reference values and interpretation. The first three have been addressed in official statements or position papers of the ATS (7–12). This statement addresses the fourth.

Focus

The charge by the ATS was to prepare a comprehensive and practical document dealing with conceptual issues and their scientific basis and providing guidelines for daily use in two areas: (*1*) selecting reference values and (*2*) interpretative strategies. The statement was to address the concerns of those who generate lung function reports and those who use lung function reports to assist in clinical case management. Epidemiologic and public health issues are not addressed though epidemiologic studies provide the scientific basis for many of the concepts used in interpreting lung function results. The ATS has published standardization procedures for epidemiologic studies (14). The focus of this statement is spirometry, but reference is made to other lung function tests when pertinent. Although the statement deals primarily with adults, the conceptual issues apply to children as well. Terms and abbreviations follow the American College of Chest Physicians (ACCP)-ATS joint committee on pulmonary nomenclature recommendations (15). The next four sections deal with conceptual issues and their scientific basis; the last section deals with practical considerations and recommendations.

Sources of Variation in Lung Function Testing

Conceptual Issues Pertinent to the Interpretation of Lung Function Tests

All clinical measurements, including pulmonary function tests, are subject to (*1*) technical variation related to instrument, procedure, observer, subject, and their interactions; (*2*) biologic variation, the focus of interest of most of the nonclinical biological sciences; (*3*) variation caused by dysfunction or disease, the focus of clinical medicine (5). In clinical pulmonary function testing, it is important to minimize the variation caused by technical factors and to take biologic variation into account so that variations caused by disease can be properly interpreted. Sources of technical and biologic variation and the estimated magnitude of their effects are listed in tables 1 and 2.

Interpretation of pulmonary function tests depends upon establishing the variation of interest (the signal) and its relation to all other sources of variation (the noise) (5). Which sources of variation constitute signal and which noise will depend on the question being asked. For instance, in a physiologic study of the effects of posture on FEV_1, variation caused by posture would constitute the signal and all other sources of within-individual variation, the noise. Similarly, in an epidemiologic study of the effects of an occupational exposure on a work force, variation caused by exposure will constitute the signal, and all other sources of between population variation, the noise. In the clinical context, signal and noise will vary according to the clinical question. For instance, when assessing the outcome of a treatment, the signal would be the change after treatment, and the noise would be within-individual variation in the absence

TABLE 1

SOURCES OF VARIATION IN LUNG FUNCTION*

Source	Determinants
Technical	Instrument, subject, posture, observer, procedure (including number of tests), software; temperature; altitude
Biologic	
Within individual	All of the above
	Diurnal (circadian) and seasonal effects, endocrinologic effects
Between individual	All of the above
	Personal factors, including size, age, sex, physical activity, muscularity, race, and other genetic characteristics and past and present health
	Environmental factors, including tobacco smoke (personal and environmental), occupation, residence (urban or rural), air pollution (home, environmental), and socioeconomic status
Between population	All of the above
	Selection factors which determine inclusion or exclusion of certain subjects from study populations

* Based on table in reference 5 and reproduced with permission.

TABLE 2

ESTIMATES OF THE PROPORTION OF MEASURED BETWEEN-INDIVIDUAL VARIATION IN FEV_1 OR FVC IN ADULTS ATTRIBUTABLE TO IDENTIFIED FACTORS*

Factor		Proportion of Variation Attributable
Sex		up to 0.30
Age	0.08	
Height	0.20	up to 0.30
Weight	0.02	
Ethnic differences		0.10
Technical		0.03
Unexplained†		0.27
Total		1.00

* Reproduced with permission from reference 5.

† Includes all other determinants of biologic variation discussed in SOURCES OF VARIATION IN LUNG FUNCTION TESTING whether environmental (e.g., smoking, active, and passive, occupational exposures, residential pollution, socioeconomic status) or host, (e.g., genetic, allergic, past and present respiratory health status). The latter two are usually the focus of interest to the clinical pulmonary function laboratory.

of treatment. When lung function tests are used as an aid in diagnosis, the signal is usually the patient's results compared with the expected result for subjects without disease but similar in the personal characteristics that determine lung function such as sex, size, age, and, possibly, race (table 1).

Technical Sources of Variation

INSTRUMENTATION

Detection of instrument problems is an integral part of interpretation. Readers should consult ATS recommendations on spirometry and D_{LCO}, which give practical limits of acceptable instrument variability (7–9). Instruments and procedures used in developing of reference values and those used to evaluate patients should meet, and preferably exceed, current ATS recommendations.

PRECISION AND ACCURACY

In considering the variability of a test, a distinction must be made between precision and accuracy. Precision refers to the repeatability of the measurements, even if the values obtained are not accurate (16). Accuracy, which is not easy to establish, refers to how close the measurements made by an instrument are to the "true" value. Because most instruments have better precision than accuracy, between-instrument variation usually contributes more to total measurement variability than within-instrument variation.

COMPUTER SOFTWARE AND HARDWARE

Overall, the use of computers in spirometry systems has reduced technical variability; nevertheless errors associated with computers occur. Even small differences in the techniques used to calculate flow can produce relatively large differences in derived flow measurements (17, 18). It is imperative that spirometry systems using computers be validated initially and each time changes are made in software or hardware. One simple method of validating computer computations is to compare manual calculations of spirometric values with computer-calculated values. The values should be close, ± 2 to 3%, but they will not be identical. Computers can also provide immediate feedback on the success of a subject's performance and improve overall test quality. Quality control algorithms that detect coughs, late peak flows, premature termination of effort, excessive extrapolated volumes using the back extrapolation technique, and excessive variation between maneuvers can be programmed to provide immediate feedback to the technician.

SPECIAL CONSIDERATIONS FOR TESTING CHILDREN

Equipment for testing children should have an accuracy for volume of ± 50 ml to below 0.5 L. The output for the hard copy display should be scaled to the size of the signal with a variable attenuation to a minimum of 30 mm/L. There should be a visible real-time display to encourage both the child and the technician and to ensure that effort is sustained over a sufficient time. Equipment, including mouthpieces and noseclips, should be adjustable and comfortable for children with heights as low as 120 cm. Children should be tested in a laboratory where personnel are familiar with clinical testing of children and where interpretations can be made by persons familiar with pulmonary function testing in children. Detailed recommendations for pediatric testing have recently been issued by the European Society of Clinical Respiratory Physiology (13).

Procedural Sources of Variation

The largest single source of within-subject variability is improper performance of the test. Therefore, interpretations of spirometry should include a statement about test quality before any other interpretation is rendered. The ATS (7–12), the ECCS (4), the California Thoracic Society (2), the Intermountain Thoracic Society (19), the European Society for Clinical Respiratory Physiology (13), and several texts (1, 3, 20–23) have all recognized the importance of procedure in reducing measurement variability. Readers should consult these references for detailed recommendations.

Biologic Sources of Variation

WITHIN-INDIVIDUAL (INTRAINDIVIDUAL) VARIATION

This section addresses short-term intraindividual variations in lung function that do not originate with instrumentation and are not related to disease, environment, the intake of drugs, smoking, or failure of the subject to inspire or expire maximally during spirometric maneuvers. The main residual sources of variation are: (*1*) body position, (*2*) head position, (*3*) effort dependence of maximal flows, and (*4*) circadian rhythms.

(*1*) *Body position.* Body position affects spirometric volumes, particularly FVC and VC, which are 7 to 8% lower in the supine than in the standing position and 1 to 2% lower in the sitting than in the standing position (24–27). Body position should be kept constant in comparison studies. The standing position may be particularly advantageous for obese subjects (28).

(*2*) *Head position.* Systematic increases in maximal expiratory flows have been documented during neck hyperextension (29). These increases are believed to be related to elongation and stiffening of the trachea and range from minimal to 35% of baseline values for lung volumes above FRC (60 to 80% of VC). Corresponding changes in FEV_1 have not been documented. Conversely, neck flexion may decrease peak expiratory flow rate (29) and increase airway resistance (30). Avoiding hyperextension and flexion of the neck seems sufficient to eliminate this source of variability. The effect of neck position is usually less than that of body position, but it may be important for patients tested in bed.

(*3*) *Effort dependency of maximal flows.* The imperative for standardization is one reason for the recommendations that the expiratory maneuver be performed with maximal effort. Nevertheless, FEV_1 may be 100 to

200 ml lower when the effort is maximal compared with submaximal efforts because the airways are narrower with respect to the exhaled volume (31–34). Variable expiratory effort may thus be a confounding factor when assessing small changes in maximal flows or timed volumes such as those resulting from bronchodilator response, therapy, or aging. When a flow-volume curve is available, peak expiratory flow may be an index of maximal expiratory effort (31). In some subjects, repeated maximal efforts may trigger bronchospasm, resulting in a progressive decrease in FVC and FEV_1 (35). This may also account for a subject's inability to achieve the reproducibility standard recommended by the ATS. It is of interest that failure to meet these reproducibility standards may itself be a measure of less than perfect health (36, 37).

(*4*) *Circadian rhythms.* Variations in lung function tests with a period of approximately 24 h are well documented (38–40). For maximal expiratory flows, the lowest values are usually seen in the early morning (4 to 6 A.M.), and the largest values are seen around noon (38). In healthy subjects, FEV_1 has been shown to increase by about 0.15 L in the morning and decrease by 0.05 L in the afternoon (39); for peak expiratory flow rate (PEFR), the peak-to-trough amplitude is on the order of 8% (40). Circadian variations have also been documented for airway resistance, specific airway conductance, functional residual capacity, total lung capacity, and residual volume (41–44). The mechanisms responsible for these diurnal variations in lung function have not yet been elucidated (45, 46). Much larger diurnal changes are seen in asthmatic patients who often exhibit a severe "morning dip" in pulmonary function parameters with decreases of 50% or more in PEFR (40, 41, 47, 48). As with healthy subjects, the largest values are usually seen around noon, but this pattern may be substantially shifted by the timing of treatment (49). Exaggerated circadian variations have also been observed in patients with chronic bronchitis (50, 51). Seasonal variations of respiratory function have also been recorded (49).

Between-Individual (Interindividual) Variability: Host Factors

The most important host factors responsible for interindividual variation in lung function are (*1*) sex and size, and (*2*) aging, which account for approximately 30, 22, and 8%, respectively, of the variation in adults (5) (table 2). Other sources of interindividual variation are (*3*) race and (*4*) past and present health. Approximately 27% of interindividual variation remains unexplained (5) (table 2).

(*1*) *Size and sex.* Size is usually measured as standing height (6, 52). Sitting height, not as easy to measure as standing height, generally explains less of the variability (53), but it may be a useful predictor in certain circumstances (e.g., when dealing with a population of mixed ethnic origins, see below). Arm span measurements provide a practical substitute for standing height in subjects unable to stand or those with a skeletal deformity such as kyphoscoliosis (19, 54). Lung function is decreased at both extremes of weight (55, 56). Including measurements of chest circumference only slightly improves the prediction of lung function (57–60). Variations in airway and air-space dimensions and geometry also contribute to interindividual variation in lung function (61, 62). Accurate methods of measuring airway and air-space geometry are not widely available, and the contribution these measurements will make to increasing prediction accuracy is unknown. After correcting for body size, girls appear to have higher expiratory flows than do boys, whereas adult men have larger volumes and flows than do women (6, 63, 64).

(*2*) *Aging.* An appropriate model for lung function changes caused by aging during the adult years includes a period after adult height is attained in which there is either an increase (usual in young men) or little or no decrease in function (usual in young women), after which the function decreases at an accelerating rate with increasing age (6, 65) (see also Growth section below). These accelerated aging effects are typically found in longitudinal studies and not in studies based on cross-sectional data. The differences between cross-sectional and longitudinal studies are explained by both statistical issues (66–69) and cohort effects (5, 6, 52, 55, 70).

(*3*) *Race.* Race has been consistently shown to be an important determinant of lung function (20, 55, 58, 63, 64, 71–83). When compared with Caucasians of European descent, values for most other races usually show smaller static and dynamic lung volumes and lower forced expiratory flow rates but similar or higher FEV_1/FVC ratios. In some population groups diffusing capacity (transfer factor) is also lower (71). Regression equations derived from white populations using standing height as the measure of size usually overpredict values measured in black subjects by about 12% for TLC, FEV_1, and FVC and by approximately 7% for FRC and RV (20). People of mixed race usually have intermediate values. These differences persist after allowances are made for age, stature, smoking, air pollution, habitual activity, and altitude. The reason for the differences between the races is unclear. Differences may be due in part to differences in body build (58, 63, 64, 72–76). Blacks, on average, have a smaller trunk:leg ratio than do whites (77). The use of sitting height as an index of body size in prediction equations reduces but does not fully eliminate the observed differences between whites and blacks (58, 63, 64, 77) or the differences between Europeans, Indians, and Asians. Environmental differences, perhaps relating to nutrition, physical activity, community air pollution, and socioeconomic factors are also thought to contribute to these differences (78–85).

(*4*) *Past and present health.* Lung function at any one point in time reflects not only the present health of the individual but also the sum of all the insults and injuries the lung has sustained in the past including those from the prenatal and immediate postnatal periods (86–88).

Between-Individual (Interindividual) Variation: Environmental Factors

The effects of exposure to tobacco smoke, by far the most important environmental factor known to alter lung function, are well documented elsewhere (89). In this section consideration is given to other environmental factors that account for between-individual differences in lung function.

(*1*) *Geographic factors.* Altitudes as high as 1,500 m do not appear to cause measurable changes in lung volumes, though measurement of some flow rates may be affected by changes in air density even at these altitudes (90–92). FEV_1 and forced expiratory flows are slightly increased at high altitudes, mainly because of the decreased density of air (93, 94). During acute exposures to altitude there may be slight reductions in VC, TLC, and FRC, most likely because of increased thoracic fluid (95). Those residing at high altitudes probably have larger lung volumes than do residents at low altitudes. The reasons are unclear because of the confounding effects of variables such as nutrition (96, 97).

(*2*) *Exposure to environmental and occupational pollution.* Exposure to airborne irritants such as ozone, nitrogen dioxide, sulfur dioxide, and sulfuric acid may produce measurable transient changes in pulmonary function tests in controlled human exposure experiments and epidemiologic studies (98–102). Those who are exercising and sensitive subgroups of the general population have increased responses. For example, short-term exposures (minutes) to high concentrations of SO_2 can trigger transient bronchoconstriction in exercising asthmatics (103). Reduced lung function levels and an increased rate of decline in lung function have been associated with long-term exposures to sulfur oxides, inhalable particles, and photochemical oxidants (100).

Environmental exposure to tobacco smoke appears to affect the lung function of children (104, 105) and, possibly, adults (106–108). More recent observations also show an effect on bronchial reactivity in children (109). The health effects of other indoor pollutants have not yet been conclusively established (110, 111). Exposure to occupational pollutants, including dusts, chemicals, gas, etc., may induce acute and chronic changes in lung function (112–114).

(*3*) *Socioeconomic status.* Adverse effects of low socioeconomic status on lung function are well documented and detectable even in industrialized countries (85, 115, 116). Low socioeconomic status is often associated with unfavorable environmental conditions such as living in polluted urban-industrial areas, increased environmental and occupational exposures, increased indoor air pollution, increased rates of respiratory illness, and decreased access to health care. Moreover, differences in lung function attributed to genetic factors may be partly or even largely attributable to differences in socioeconomic status (84).

Growth

Growth affects the relationships between indices of body size and spirometric measurements in children and adolescents. Some of the determinants of lung volumes and ventilatory flows are therefore briefly reviewed here.

(*1*) *Relationship to height.* The relationship of ventilatory function to height from childhood through late adolescence to adulthood is not linear. Prediction equations for children are usually based on power or exponential functions of height, both of which seem to fit the data equally well (63, 64, 117–120).

(*2*) *Age-dependence.* Growth in standing height, measured in cross-sectional or longitudinal population studies, is not in phase with lung growth during the adolescent growth spurt (120–125). Growth in chest dimensions lags behind that of the legs (60, 122, 124, 125). In boys, standing height and VC are often not maximal by 17 yr of age (123). VC continues to increase after growth in height ceases and may not be maximal until after 25 yr of age. Girls, however, seem to attain their maximal values at about 16 yr of age (120, 122, 123). In younger subjects, FVC and FEV_1 seem to track constant percentiles over time (126). Ideally, developmental rather than chronologic age should be included in prediction equations for children and adolescents, but such equations are not available or practical.

(*3*) *Respiratory muscles.* The opposing effects of increasing muscularity and obesity have been invoked to explain the observed increase in ventilatory function that parallels increase in body mass and the decline in lung function beyond an optimal weight (55). Likewise, an increase in lung volumes and body mass when growth in height had stopped has been attributed to an increase in muscle mass and the consequent increase in respiratory muscle force (124, 127, 128). However, data on maximal inspiratory and expiratory pressures generated at different ages are inconclusive. No differences were observed between respiratory pressures in adolescents and adults (129). In adolescents there is evidence of only a small increase in maximal respiratory pressure with growth of the lung and thorax (130–134). The average maximal respiratory pressures of boys are larger than those of girls (130–133). Although there is a large variability in maximal inspiratory and expiratory pressures between individuals of the same sex, respiratory force accounts for only a small portion of the differences in ventilatory function (134, 135).

(*4*) *Elastic properties.* From the neonatal period to old age, the thoracic cage grows stiffer (136). Lung recoil increases from birth to adulthood and then decreases with aging (136–143). The relatively constant FRC/TLC ratio (120) and the measurements of respiratory system mechanical properties (136) suggest that changes in lung and chest recoil are well balanced during growth.

(*5*) *Lung volumes and ventilatory flows.* From childhood to adulthood the FEV_1/FVC ratio and the ratio of maximal expiratory flow (derived from flow-volume curves) to the FVC are almost constant. Girls generate larger expiratory flows than do boys of the same age and stature (120, 127, 135, 144, 145). This is due in part to the fact that girls have a smaller VC for the same TLC than do boys, but it may also reflect both the smaller muscle mass and the smaller number of alveoli found in girls (146). Airway tone appears to decrease in girls but not in boys after a deep inspiration (147). Finally, in children between 2 and 12 yr of age airway resistance is less in girls than in boys (148). These observations warrant using different prediction equations for boys and girls at all ages.

Statistical Considerations in the Derivation of Prediction Equations

General Comments

Reference equations provide a context for evaluating the pulmonary function values of an individual patient or subject in comparison to the distribution of measurements in a reference population. The clinician's request for tests often contains the implicit question: Are these results below the "lower limit of normal?" This section deals with statistical aspects and limitations of this concept.

Characterizing the Distribution and Determinants of Lung Function in Reference Populations

Subjects with similar characteristics for the variables that affect lung function (sex, age, height, race) can be grouped together in a stratum or a cell. Comparing the performance of an individual subject with the values generated from a reference population requires one to know something about the data in the appropriate cell, specifically: (*1*) the number in the cell, (*2*) measures of central tendency such as the mean value, (*3*) estimates of dispersion such as variance or standard deviation (SD), and (*4*) information about the symmetry of the distribution. If the number of subjects in each cell is sufficient, lung function can be described by providing descriptors of the distribution such as mean and SD. Such tabulations are infrequently used for lung function because there are too many possible cells (consider all possible combinations of age and height). Regression equations are an economical and efficient alternative method to describe expected values as a function of sex, height, and age. Regression techniques assume that pulmonary function varies in a symmetric fashion about the mean value in each cell and that the variance about the mean is constant from one cell to another. The closer the distribution of pulmonary function values comes to symmetry or, better still, to a Gaussian distribution within cells, the more it is possible to take advantage of the simplifications possible with Gaussian data.

Evaluating Prediction Equations

Linear regression is the most common but not the only model used to describe pulmonary function data in adults. Such equations perform less well at the edges of the data distribution and in those cells where there are few data. Estimates are likely to be misleading if they go beyond the range of the independent variables used to create the equation. Regression analyses are often simplified by restricting the range of possible values to cells (ranges of height and age) in which reasonable predictions are possible. One approach to regression analysis is to use separate simple regression equations for several different age groups (149, 150). This approach may introduce conflicting estimates at the points of transition between equations.

Complex equations may provide more biologically plausible models and reduce the average differences between observed and predicted values for every cell (e.g., age and height) in comparison with simple linear equations. The improved predictions, however, usually come at the cost of increased complexity of computation.

The most commonly reported measures of how well regression equations fit the data they describe are the square of the correlation coefficient (r^2) and the standard error of the estimate (SEE). The proportion of variation in the observed data explained by the independent variables is measured by r^2. The SEE is the average SD of the data around the regression line. SEE will decrease and r^2 will increase as regression methods diminish the differences between predicted and observed pulmonary function values in the reference population. When the same equations are used to describe a different population, SEE will invariably be larger, and r^2 will be smaller. In addition, since these statistics reflect average characteristics of the regression, r^2 and SEE may not reflect the ability of the equation to describe the tails of the distribution or the limits of "normal," and therefore are not sufficient criteria on which to choose the best equations to evaluate a clinical population.

Distributions and "Lower Limits of Normal"

Distributions of FEV_1 and FVC in population studies are usually found to be close to Gaussian in the middle age range, but not at the extremes. Distributions of flow measurements and ratio measures (e.g., FEV_1/FVC) are usually not symmetric (149). Transformation or age statification of the data may help produce symmetric distributions about the mean. Ideally, publications describing reference populations should include not only the prediction equations but also a means of defining their lower limits. In the absence of explicit recommendations, a lower limit can be estimated from a regression model. For spirometry, values below the fifth percentile are taken as below the expected range (below the "lower limit of normal"), and those above the fifth percentile are taken as within the expected range (149, 150). Percentiles can be calculated directly from the data if there are sufficient measurements within each category (56, 149, 150). If individual observations have a distribution close to Gaussian, the value of the fifth percentile can be roughly estimated as: Lower limit of normal = Predicted value $-1.645 \times$ SEE. Ideally, the SD of the residuals should be constant for all cells. This is true for some equations for adults (149). In other studies, the estimated SD for the logarithm of FVC and FEV_1 among preadolescent children, and for height-adjusted FVC and FEV_1 among adults, appears to be constant for each sex and race (56). If SD is proportional to the predicted mean value, as it may sometimes be in children (126), the fifth percentile can be estimated as a constant proportion of the predicted mean, i.e., a percent of predicted. A comparison of several prediction equations for spirometry has shown substantial agreement using the fifth percentile criterion but not using the $-1.645 \times$ SEE criterion (151).

Sources, Uses, and Selection of Reference Values

General Comments

Normal ventilatory function has come to mean the average spirometric values of a representative sample of healthy subjects drawn from the general population. Various criteria for excluding study subjects have been suggested based on (*1*) past and present medical history (e.g., presence of respiratory symptoms such as cough, sputum production, and wheezing; presence of physician-diagnosed respiratory disease such as asthma, bronchitis, emphysema, or tuberculosis; hospitalization for lung or chest conditions; the presence of heart disease; employment exposures; and cigarette smoking); (*2*) physical examination; and (*3*) chest radiographic findings. The most important selection criteria are those based on a history of past disease and respiratory symptoms. A reference population should, ideally, be representative of the general population from which the clientele of the laboratory comes. Although a random sample of a population is ideal, one report found that once hospital patients were excluded, the method for selecting the study sample used to generate reference values had relatively little effect on either the mean value or the range of values obtained (152).

Sources of Reference Equations

In the 1960s, a number of reference equations were published based on data gathered in specific population groups such as laboratory personnel, workers in a particular industry, school populations, subjects attending a specific clinic, volunteers, and general industrial workers (153–157). Some are derived from population-based data gathered in epidemiologic studies carried out for other purposes; in these studies reference equations are a byproduct (56, 63, 126, 149, 150). Others are based on data gathered specifically for the creation of reference equations (91, 158).

Determination of the "Normal Range"

Fixed Percent of Predicted Values

The practice in many clinical laboratories has been to classify values of FVC and FEV_1 less than 80% of predicted as abnormal. This fixed value has no statistical basis in adults (91, 159–162). Although some studies have shown that for adults of average age and height, 80% of predicted FVC and FEV_1 is close to the fifth percentile, use of a fixed value will result in shorter, older subjects being more readily classified as "abnormal" (159, 162), whereas taller, younger adult subjects are more likely to be erroneously classified as "normal." The practice of using 80% of predicted as the lower limit of normal for $FEF_{25-75\%}$ or the instantaneous flows will also cause important errors since, for these flows, the lower limits of normal are closer to 50% of predicted (149, 150). The practice of using a fixed percent of predicted as a lower limit of normal may be acceptable in children (163) (see section on Distributions and Lower Limits of Normal).

FEV_1/FVC Ratio

Defining a fixed FEV_1/FVC ratio as a lower limit of normal is not recommended in adults because FEV_1/FVC is inversely related to age and height (91, 149, 150). The use of a fixed ratio will therefore result in an apparent increase in the prevalence of impairment associated with aging or with age-confounded factors such as cigarette smoking or occupational exposures. In addition, some athletes have values for FVC that are relatively larger than those for FEV_1, resulting in a lower FEV_1/FVC. This may also be true of workers in some physically demanding occupations such as mining and deep-sea diving.

Percentiles as the "Lower Limit of Normal"

One statistically acceptable approach for establishing lower limits for any spirometric measure is to define the lowest 5% of the reference population as below the lower limit of normal (see section on Distributions and Lower Limits of Normal). This implies a 5% false positive misclassification, a rate generally considered acceptable.

Smoking as an Independent Variable

Subjects who smoke cigarettes usually have lower values for spirometry and forced expiratory flows even if they meet the same health criteria for "normal" as nonsmokers (164). Smoking has both biologic and technical effects on D_{LCO} (9, 165). A clear choice for the most appropriate method of adjusting spirometric indices for the effect of smoking is not readily evident from published data in which any of the following have been used: smoking status (current smoker or exsmoker), amount currently smoked, duration of smoking, and pack-years of smoking. Neglecting the correlation of some of these factors (e.g., pack-years) with age can introduce errors in analyzing the effect of smoking. In one study, the lifetime loss of FEV_1 for the average male smoker was 7.4 ml/pack-year, and for the average female smoker it was 4.4 ml/pack-year (164). Current smoking also adds an acute deficit in FEV_1 of approximately 150 ml over and above the cumulative effect of lifetime smoking (164, 166).

The distribution of a smoking variable in the reference population and its relation to other health indicators will affect the regression term calculated for smoking. For example, in one study a twofold greater deficit in spirometric measurements in relation to pack-years was found in subjects with chronic cough compared with those without chronic cough (167). The mean spirometric value may not be the best index for determining lung function deficit caused by smoking since the effect on the susceptible minority tends to be overwhelmed by the unaffected majority (168). Whether the effects of smoking are similar across other independent variables such as sex and age is unknown. Some of the sex differences in smoking-associated pulmonary dysfunction may be related to differences in smoking behavior (169). The effect of smoking also increases with age (166). The effect of smoking on the developing lung is likely to be different from the effect of smoking on the adult lung.

Finally, the effects of smoking cessation on pulmonary function are inconsistent. Exsmokers are found to have both reversible and irreversible ventilatory decrements (164, 166, 170). Most cross-sectional studies in older subjects have found older exsmokers to have values intermediate between those who continue to smoke and those who have never smoked. Young exsmokers may exhibit higher spirometric values than never smokers, probably as a result of health selection effect (134, 171). Whether the pulmonary function of ex-smokers is better or worse than that of current smokers probaby depends on the age of the subjects, how long they have smoked, and on why they abandoned smoking.

Cross-sectional and Longitudinal Predictions

Cross-sectional data are subject to a bias called "cohort" effect. A person who is 40 yr of age today is different from one who became 40 two decades ago because of a variety of host and environmental factors (6, 52). The age-related lung function deficit predicted from cross-sectional data tends to be greater than that predicted from longitudinal pulmonary function data in adults (67–70) and children (172–174). Prediction equations based on cross-sectional data are appropriate for determining the prevalence of pulmonary function impairment in defined populations. They are less well-suited to determine age-related events including the incidence or progression of impairment. Percentiles of adjusted lung function (similar to those used by pediatricians to assess growth) have been advocated by several investigators for assessment of both growth and decline of pulmonary function (56, 63, 126). A person would be expected to track along the same percentile as he or she ages if the loss (gain) in function was at a rate comparable to that of the reference population.

Criteria for Selection of Reference Values

Criteria for selecting reference values to be used in the clinical or in the epidemiologic context fall into three categories: methodologic, epidemiologic, and statistical (5).

(*1*) *Methodologic criteria.* If possible, reference values should be based on data obtained by trained operators using equipment and techniques that meet ATS criteria (7–12). In contrast with the use of the FVC in America, predictions of VC from Europe are usually based on inspiratory vital capacity (IVC) or slow expiratory vital capacity (EVC). The IVC and EVC are, on average, somewhat larger than FVC in healthy subjects; in subjects with airflow limitation, the differences are more pronounced (4, 175).

(*2*) *Epidemiologic criteria.* The population from which the subjects are drawn should be similar with respect to age, height, sex, and ethnic composition to the population to whom the prediction values are to be applied. Prediction equations should use age, height, sex, and, probably, ethnic group as independent variables. For most clinical uses they should be based on cross-sectional studies of lifetime nonsmokers.

(*3*) *Statistical criteria.* These are discussed in STATISTICAL CONSIDERATIONS IN THE DERIVATION OF PREDICTION EQUATIONS. Both biologic plausibility and simplicity in the model used to develop prediction equations are important issues in the selection of reference values. However, neither is as important as the choice of a reference population that (*1*) provides an appropriate comparison for the subjects to be evaluated, and (*2*) is based on measurements made with instruments and methods comparable to those used in the laboratory for which reference values are being selected (2, 5).

Published Reference Equations

For the convenience of readers, selected published reference equations for adult whites and blacks and scaling factors for blacks currently in use are listed in tables 3 to 9. A comprehensive listing up to 1983 was published by the ECCS (4). The results of a survey of reference equations used in North American pulmonary teaching centers is shown in table 10. Equations for children and adolescents are detailed elsewhere (13, 63, 117–119, 131, 149, 176, 177). Laboratories should use the published reference equations that most closely describe the populations tested in their laboratories. This may also be assessed empirically by comparing the results for a group of 20 to 40 local reference subjects with those provided by the intended reference equations. The local reference subjects should be appropriately selected by age, ethnic group, and sex, to match the clientele of the laboratory and should meet the selection criteria listed in section CRITERIA FOR SELECTION OF REFERENCE VALUES.

Limitations of Currently Available Equations

Reference equations now available include relatively few results for adolescents and the elderly. Even fewer equations span the ages from grade school through adulthood and, with few exceptions, they are discontinuous for children and adults (55, 178). Older subjects reflect their lifetime experiences with respect to nutrition, health status, and other factors and are therefore subject to a cohort effect. Most equations in current use are based on linear statistical models. All these aspects are subject to change. For this reason, reference equations should be reviewed regularly.

Interpretative Strategies

Conceptual Issues Concerning Normality and the Limits of Normal

The word "normal" is used in a number of ways (5, 6, 13, 179). In popular use it means ideal, conventional, or usual. It is used by statisticians to describe a specific distribution about a central tendency and by biologists in ways that vary according to their focus of interest. Anatomists, for instance, use it to describe structural variations consistent with good function; physiologists use it to describe variations that preserve the "internal milieu," and clinicians use it to describe variation within the limits of "good health" and exclusive of "disease" (5). Issues of biologic "normality" are discussed in greater detail elsewhere, and interested readers are referred to those reviews (5, 6, 179–181).

Because most laboratory tests are quantitative variables with overlap between measurements in healthy and diseased subjects, the idea of a range of values defining biologically "normal" is, in the view of its critics, misleading (5, 6, 182). For instance, in interpreting laboratory test results where there is an overlap between healthy and diseased populations, the "normal" range should theoretically change with different disease processes and with the clinical questions being asked (181). It has also been pointed out that selecting a normal range "requires careful evaluation of benefit in terms of morbidity or mortality, inconvenience, and distress caused to

TABLE 3

PREDICTED VALUES FOR FEV_1 AND FVC DERIVED FROM SELECTED STUDIES OF NONSMOKING CAUCASIAN MEN*

First Author, Year (Ref)	Age Range (*yr*)	Number Studied	FEV_1† for Ht 1.75 m, Age 45 yr	Regression Coefficient		RSD or SEE	FVC† for Ht 1.75 m, Age 45 yr	Regression Coefficient		RSD or SEE
				Ht	Age			Ht	Age	
Morris, 1971 (224)	20–84	517	3.63	3.62	−0.032	0.55	4.84	5.83	−0.025	0.74
Cherniack, 1972 (225)	15–79	870	3.74	3.59	−0.023	NR	4.52	4.76	−0.014	NR
Quanjer, 1977 (4)	21–64	189	3.59	4.05	−0.031	0.43	4.51	6.11	−0.032	0.56
Crapo, 1981 (91)	15–91	125	3.96‡	4.14	−0.024	0.49	4.89‡	6.00	−0.021	0.64
Knudson, 1983 (149)	25–84	86	3.81	6.65	−0.029	0.52	4.64	8.44	−0.030	0.64
Dockery, 1985 (56)	25–74	624	3.78	Equation nonlinear§		0.40	4.72	Equation nonlinear§		0.47
Roca, 1986 (226)	20–70	443	3.95	4.99	−0.021	0.44	5.15	6.78	−0.015	0.53
Paoletti, 1986 (150)	29–64	59	3.83	4.94	−0.027	0.48	5.06	7.24	−0.027	0.58
Miller, 1986 (158)	18–85	176	3.94	5.66	−0.023	0.41	4.84	7.74	−0.021	0.51

Definition of abbreviations: RSD = residual standard deviation; SEE = standard error of the estimate; NR = not reported.

* To be included studies had to (*1*) include men and women; (*2*) adequately describe the methods used; (*3*) analyze spirometric values in terms of age and height. Instruments of measurement were: water spirometer (56, 91, 224); dry or wedge spirometer (158, 225); pneumotachograph (4, 149, 150, 226). Equation to predict FEV_1 or FVC using this table:

Predicted FEV_1 or FVC = Predicted value† for Ht 1.75 m, Age 45 + Ht Coefficient × (Ht − 1.75) + Age Coefficient × (Age − 45)

† Predicted value for Ht = 1.75 m, Age = 45.

‡ Studies carried out at an altitude of 1,400 m.

§ $FEV_1 = Ht^2 (1.541 - 4.06 \times 10^{-3}\ Age - 6.14 \times 10^{-5}\ Age^2)$; $FVC = Ht^2 (1.75 - 1.35 \times 10^{-4}\ Age - 1.01 \times 10^{-4}\ Age^2)$.

TABLE 4

PREDICTED VALUES FOR FEV_1 AND FVC DERIVED FROM SELECTED STUDIES OF NONSMOKING CAUCASIAN WOMEN*

First Author, Year (Ref)	Age Range (yr)	Number Studied	FEV_1,† for Ht 1.65 m, Age 45 yr	Regression Coefficient Ht	Regression Coefficient Age	RSD or SEE	FVC† for Ht 1.65 m, Age 45 yr	Regression Coefficient Ht	Regression Coefficient Age	RSD or SEE
Morris, 1971 (224)	20–84	471	2.72	3.50	−0.025	0.47	3.54	4.53	−0.024	0.52
Cherniack, 1972 (225)	15–79	452	2.87	2.37	−0.019	NR	3.36	3.08	−0.015	NR
Quanjer, 1977 (4)	21–64	514	2.71	3.17	−0.031	0.35	3.39	4.64	−0.027	0.42
Crapo, 1981 (91)	15–84	126	2.92‡	3.42	−0.026	0.33	3.54‡	4.91	−0.022	0.39
Knudson, 1983 (149)	20–87	204	2.79	3.09	−0.020	0.39	3.36	4.27	−0.017	0.49
Dockery, 1985 (56)	25–74	1,830	2.79	Equation nonlinear§		0.40	3.41	Equation nonlinear§		0.47
Roca, 1986 (226)	20–70	427	2.87	3.17	−0.025	0.31	3.72	4.54	−0.021	0.40
Paoletti, 1986 (150)	21–64	313	2.84	2.43	−0.020	0.29	3.78	4.12	−0.015	0.39
Miller, 1986 (158)	18–82	193	2.91	2.68	−0.025	0.33	3.59	4.14	−0.023	0.45

* To be included studies had to (1) include men and women; (2) adequately describe the methods used; (3) analyze spirometric values in terms of age and height. Instruments of measurement were: water spirometer (56, 91, 224); dry or wedge spirometer (158, 225); pneumotachograph (4, 149, 150, 226). Equation to predict FEV_1 or FVC using this table:

Predicted FEV_1 or FVC = Predicted value† for Ht 1.65 m, Age 45 + Ht Coefficient × (Ht − 1.65) + Age Coefficient × (Age − 45)

† Predicted value for Ht = 1.65 m, Age = 45 yr.
‡ Studies carried out at an altitude of 1,400 m.
§ $FEV_1 = Ht^2 (1.332 - 4.06 \times 10^{-3} Age - 6.14 \times 10^{-5} Age^2)$; $FVC = Ht^2 (1.463 - 1.35 \times 10^{-4} Age - 1.01 \times 10^{-4} Age^2)$.

TABLE 5

PREDICTED VALUES FOR FEV_1 AND FVC DERIVED FROM SELECTED STUDIES OF BLACK MEN AND WOMEN*

First Author, Year (Ref)	Age Mean or Range	Number Studied	FEV_1 for Ht and Age†	Regression Coefficients Ht	Regression Coefficients Age	RSD or SEE	FVC for Ht and Age†	Regression Coefficients Ht	Regression Coefficients Age	RSD or SEE
Men			Ht 1.75 m Age 45 yr				Ht 1.75 m Age 45 yr			
Johannsen, 1968 (227)	20–50	120	2.96‡	2.87	−0.017	0.46	4.07‡	4.09	—	0.52
Miller, 1970 (228)	35–54	96	3.05	3.40	−0.024	0.37	3.79	4.44	−0.024	0.46
Oscherwitz, 1972 (81)	50.3 ± 6.6	110	2.94	2.99	−0.031	0.64	3.78	3.70	−0.027	0.68
Rossiter, 1974 (229)	21–70	147	3.04	4.51	−0.027	0.52§	3.84	5.77	−0.019	0.59§
Lapp, 1974 (230)	34.9 ± 11.9	79	3.53	3.54	−0.025	0.23	4.11	3.94	−0.021	0.32
Cookson, 1976 (231)	43.6 ± 15.1	141	3.12	2.20	−0.024	0.50	3.74	3.90	−0.017	0.65
Patrick, 1976 (232)	18–65	213	3.11	4.23	−0.023	NR	3.72	3.51	−0.025	NR
Women			Ht 1.65 m Age 45 yr				Ht 1.65 m Age 45 yr			
Johannsen, 1968 (227)	20–50	100	2.25‡	2.18	−0.013	0.34	2.74‡	2.51	−0.015	0.35
Miller, 1970 (228)	35–54	109	2.19	2.45	−0.018	0.31	2.74	3.15	−0.020	0.38
Cookson, 1976 (231)	36.7 ± 11.6	102	2.35	2.40	−0.028	0.41	2.86	3.00	−0.019	0.42
Patrick, 1976 (232)	18–65	117	2.10	1.49	−0.014	NR	2.64	3.17	−0.020	NR

* Instruments of measurement used were: water spirometer (227, 229, 231), a dry or bellows spirometer (228, 230), and various others (81, 232). Predicted values for men and woman are calculated as shown in footnotes to tables 3 and 4.
† Predicted value for a 45-yr-old man 1.75 m tall, and a 45-yr-old woman 1.65 m tall.
‡ Corrected from ATPS to BTPS conditions, assuming a spirometer temperature of 22° C.
§ Includes caucasian subjects.

subjects by further investigation and treatment, and the costs of making the wrong decision" (182). The "normal" range only gives information about the distribution of test results in the healthy population from which they were derived. It says nothing about the true positive rate, the false negative rate, or the predictive power of a positive test.

To draw inferences about the presence of disease from a test, one should, ideally, know the prior probability that the patient has the disease and the distributions of test values for subjects with and without the disease in question. Although this ideal is rarely met, clinicians must use their understanding of the clinical situation to put an interpretation in proper perspective.

Obstructive and Restrictive Ventilatory Defects

Definition of an Obstructive Defect

An obstructive ventilatory defect may be defined as a disproportionate reduction of maximal airflow from the lung with respect to the maximal volume (VC) that can be displaced from the lung. It indicates airflow limitation and implies airway narrowing during expiration. The earliest change associated with flow limitation in small airways is thought to be slowing in the terminal portion of the spirogram even when the initial part of the spirogram is unaffected (1, 21–23). This slowing is reflected in a proportionally greater reduction in the instantaneous flow measured after 75% of the FVC has been exhaled (FEF_{75}) or in $FEF_{25-75\%}$ than in FEV_1. Abnormalities in these midrange flow measurements during a forced exhalation are, however, not specific for small airway disease and, though suggestive, should not be used to diagnose small airway disease in individual patients (183). As airway disease becomes more advanced and/

TABLE 6

PREDICTED VALUES FOR FEV$_1$/FVC% DERIVED FROM SELECTED STUDIES OF CAUCASIAN AND BLACK MEN AND WOMEN*

First Author, Year (Ref)	Age Range (yr)	Number Studied	FEV$_1$/FVC%† for Ht 1.75 m and Age 45 yr	Regression Coefficients		RSD or SEE	Number Studied	FEV$_1$/FVC%† for Ht 1.65 m and Age 45 yr	Regression Coefficients		RSD or SEE
				Ht	Age				Ht	Age	
			Caucasian Men					Caucasian Women			
Quanjer, 1977 (4)	21–64	189	78.4	—	−0.16	5.3	514	80.2	—	−0.24	6.4
Crapo, 1981 (91)	15–91	125	80.9‡	−13.0	−0.15	4.8	126	81.9‡	−20.2	−0.25	5.3
Knudson, 1983 (149)	25–85	86	82.0	—	−0.11	6.3	204	82.6	−18.5	−0.19	7.6
Paoletti, 1986 (150)	8–64	263	75.9	−5.3	−0.23	6.1	538	70.5	−4.3‖	−0.31	5.8
Miller, 1986 (158)	18–85	176	80.5	−13.1	−0.15	5.6	193	82.3	−21.5	−0.15	6.8
			Black Men					Black Women			
Johannsen, 1968 (227)	20–50	120	75.0	—	−0.29	8.6					
Oscherwitz, 1972 (81)	50.3 (± 6.6)	110	77.7	4.2	−0.32	10.2					
Rossiter, 1974 (229)	21–70	147	77.2	0.62	−0.34	7.2§					
Cookson, 1976 (231)	43.6 (± 15.1)	141	81.4	—	−0.25	10.7	102	82.3	—	−0.38	11.7

* Table comprises studies cited in tables 3 to 5, which also reported values for FEV$_1$/FVC% analyzed in relation to height and age. For the instruments of measurement used, see footnotes to tables 3 to 5. Note: studies of Caucasian subjects were confined to nonsmokers; studies of black subjects included all smoking categories. Predicted values for FEV$_1$/FVC are calculated as shown in footnotes to tables 3 and 4. Only one study gives equations for black women.

† Predicted value for a 45-yr-old man 1.75 m tall, and a 45-yr-old woman 1.65 m tall.

‡ Studies carried out at an altitude of 1,400 m.

§ Includes Caucasian subjects.

‖ Coefficient not significant.

TABLE 7

PREDICTED VALUES FOR DIFFUSING CAPACITY (D_{LCO}) AND KCO (D_{LCO}/V_A) DERIVED FROM SELECTED STUDIES OF MEN AND WOMEN*

First Author, Year (Ref)	Age Mean ± SD or Range	Number Studied	D_{LCO}† for Ht and Age	Regression Coefficients		RSD or SEE	D_{LCO}/V_A† for Ht and Age	Regression Coefficients		RSD or SEE
				Ht	Age			Ht	Age	
Men			Ht 1.75 m, Age 45 yr				Ht 1.75 m, Age 45 yr			
Billiet, 1963 (233)	20–75	57	35.3	57.6	−0.24	4.2	4.96	—	−0.04	0.92
Cotes, 1965 (20)	19–72	127	30.3	32.5	−0.20	5.1	4.83	—	−0.04	0.81
Teculescu, 1970 (234)	19–67	47	32.6	33.3	−0.30	4.2	5.17‡	—	−0.04	0.73
Van Ganse, 1972 (235)	25–79	70	29.3	16.4	−0.20	3.8	5.60	−0.90	−0.03	1.07
Frans, 1975 (236)	39 ± 12	64	33.3	28.5	−0.14	4.2	NR			
Marcq, 1976 (237)	17–79	64	29.9	10.4	−0.20	3.9	4.59	—	−0.03	0.65
Salorinne, 1976 (238)	20–69	69	30.7	14.2	−0.23	3.6	5.02	−3.53	−0.03	0.63
Crapo, 1981 (239)	15–91	123	36.6§	41.6	−0.22	4.8	5.45§	—	−0.03	0.84
Miller, 1983 (165)	43 ± 16	74	31.4	16.4	−0.23	4.8	4.77	−2.24	−0.03	0.73
Paoletti, 1985 (240)	19–64	80	37.1‖	44.1	−0.19	5.8	4.81‖	−0.12††	−0.02	0.71
Knudson, 1987 (241)	25–84	71	38.4‖	35.5	−0.27	4.6	5.61‖	−2.35††	−0.04	0.80
Roca, 1990 (242)	20–70	194	33.6	36.7	−0.20	4.4	Equation nonstandard¶			
Women			Ht 1.65 m, Age 45 yr				Ht 1.65 m, Age 45 yr			
Billiet, 1963 (233)	20–68	41	25.2	21.9	−0.16	3.6	5.55	—	−0.03	0.85
Van Ganse, 1972 (235)	24–76	72	20.3	16.8	−0.16	3.6	5.61	−0.17	−0.01	0.99
Salorinne, 1976 (238)	20–69	101	25.0	21.9	−0.12	2.8	5.27	−3.96	−0.01	0.74
Hall, 1979 (243)	27–74	113	30.1**	28.3	−0.19	4.1	5.66**	—	−0.02	0.74
Crapo, 1981 (239)	17–84	122	27.4§	25.6	−0.14	3.6	5.46§	—	−0.03	0.78
Miller, 1983 (165)	43 ± 15	130	23.7	16.0	−0.11	4.0	4.62	−1.81	−0.02	0.80
Paoletti, 1985 (240)	18–64	291	27.9‖	15.7	−0.07	4.3	4.85‖	−2.51	−0.02	0.85
Knudson, 1987 (241)	20–86	99	28.2‖	18.7	−0.15	4.5	5.37‖	−2.78††	−0.03	0.85

* Table refers to D_{LCO} and includes predicted values from published reports in which the number of subjects studied and their age were given and in which equations for D_{LCO} were described in terms of height and age according to ATS recommendations (9). All but one study (20) refer to nonsmokers. Residual volume or FRC was measured as follows: single-breath helium dilution (165, 234, 236–242), multiple-breath helium dilution (20, 233, 243), open circuit N_2 washout (235). Predicted values for D_{LCO} and D_L/V_A are calculated as shown in footnotes to tables 3 and 4.

† Predicted value for a 45-yr-old man 1.75 m tall, and a 45-yr-old woman 1.65 m tall.

‡ Results adjusted to 1 BTPS.

§ Measurements made at an altitude of 1,400 m.

‖ Correction for breathholding time as in the Epidemiology Standardization Project (240, 241). Note that calculated D_L is sensitive to the methods used to calculate breathhold time.

¶ Form of the equation not that recommended by the ATS.

** Results calculated for all smoking categories and adjusted for smoking effect.

†† Coefficient not significant.

TABLE 8

PREDICTED VALUES FOR TOTAL LUNG CAPACITY (TLC) AND RESIDUAL VOLUME (RV) DERIVED FROM SELECTED STUDIES OF MEN AND WOMEN*

First Author, Year (Ref)	Age Mean or Range	Number Studied	TLC† for Ht and Age	Regression Coefficients Ht	Regression Coefficients Age	RSD or SEE	RV† for Ht and Age	Regression Coefficients Ht	Regression Coefficients Age	RSD or SEE
Men			Ht 1.75 m, Age 45 yr				Ht 1.75 m, Age 45 yr			
Goldman, 1959 (92)	44 ± 17	44	6.61	9.40	−0.015	0.65	2.04	2.70	0.017	0.39
Cotes, 1965 (20)	19–72	127	6.68	8.67	—	0.91	Not reported			
Boren, 1966 (155)	20–62	422	6.35	7.80	—	0.87	1.62	1.90	0.012	0.53
Black, 1974 (244)	16–59	83	6.84	7.80	—	0.68	2.15	3.80	0.034	0.57
Crapo, 1982 (245)	15–91	123	6.72	7.95	0.003	0.79	1.87	2.16	0.021	0.37
Women			Ht 1.65 m, Age 45 yr				Ht 1.65 m, Age 45 yr			
Goldman, 1959 (92)	38 ± 16	50	5.18	7.90	−0.008	0.53	1.78	3.20	0.009	0.37
Grimby, 1963 (246)	18–72	58	5.05	7.31	−0.016	0.52	1.44	2.92	0.008	0.35
Black, 1974 (244)	16–59	110	5.20	6.40	—	0.62	1.76	2.30	0.021	0.46
Hall, 1979 (243)	27–74	113	5.30	7.46	−0.013	0.51	1.80	2.80	0.016	0.31
Crapo, 1982 (245)	17–84	122	5.20	5.90	—	0.54	1.73	1.97	0.020	0.38

* Only one (245) of these studies conforms strictly to the ATS recommendations for spirometry (8); references 20, 155, 243, 244 included all smoking categories, and in two (92, 246) smoking status was not defined. Residual volume was measured as follows: helium rebreathing (20, 92, 243, 246), whole-body plethysmograph (244), single-breath helium dilution (245), and helium rebreathing on open circuit N_2 washout in one study (155). Predicted values for TLC and RV are calculated as shown in footnotes to tables 3 and 4.

† Predicted value for a 45-yr-old man 1.75 m tall, and a 45-yr-old woman 1.65 m tall.

or more proximal airways become involved, timed segments of the spirogram such as the FEV_1 will become reduced out of proportion to the reduction in VC.

Definition of a Restrictive Defect

A restrictive ventilatory defect is characterized physiologically by a reduction in TLC. One may infer the presence of a restrictive ventilatory defect when VC is reduced and FEV_1/FVC is normal or increased. Severe airflow limitation is another common cause of a reduced VC either because airflow is so slow the subject cannot continue to exhale long enough to complete emptying or because airways collapse. Occasionally, patients will have a small VC, a normal FEV_1/FVC, and a normal TLC. If there is a contradiction between VC and TLC in defining restriction the classification should be based on TLC.

Bronchodilator Response

Bronchial responsiveness is an integrated physiologic mechanism involving airway epithelium, nerves, mediators, and bronchial smooth muscle. Because the within-individual difference in response to a series of different bronchodilators is variable, and as many as 20 to 30% of responsive subjects will respond to one type of agent but not to another (184), the assumption that a single test of bronchodilator response is adequate to assess both the underlying airway responsiveness and the potential for therapeutic benefits of bronchodilator therapy is overly simplistic (185). The correlation between bronchoconstriction and bronchodilator responses is imperfect, and it is not possible to infer with certainty the presence of one from the other.

Data on the percent change in FVC, FEV_1, and $FEF_{25-75\%}$, after bronchodilator administration in general population studies as well as in patient populations are summarized in table 11. These studies showed a tendency for the calculated bronchodilator response to increase with decreasing baseline VC or FEV_1, whether response was considered as an absolute change or as a percent of the initial value. Bronchodilator responses in patient-based studies are, not surprisingly, somewhat higher than those in general population studies (table 11).

Interpretation of change after a bronchodilator should be made in light of the clinical question. If the question is whether a patient has an increased bronchodilator response, the appropriate reference is probably one of the population-based studies. If the question is whether the patient is different from other patients or from previous visits, patient groups may provide the most appropriate reference data.

There is no clear consensus on what constitutes reversibility in subjects with airflow obstruction (192). In part, this is because there

TABLE 9

FACTORS FOR ADJUSTING REFERENCE VALUES FOR CAUCASIANS WITH A VIEW TO THEIR BEING USED FOR BLACK AMERICANS*

FEV_1	0.88†
FVC	0.88†
FEV_1/FVC	0
TLC	0.88
RV	0.93‡
RV/TLC	1.05
Diffusing Capacity (transfer factor)	0.93
TI/VA (BTPS)	1.05

* Source: Rossiter and Weill with annotation (229). Although the average Caucasian admixture in studies of Black Americans varies, a reasonable average is 22% (247).

† Also apply to women younger than 55 yr of age; in older subjects, the correction may be larger (approximately 0.80; Dockery *et al.* [56]).

‡ A larger correction (approximately 0.88) was proposed by Lapp *et al.* (230).

TABLE 10

SURVEY OF SPIROMETRY REFERENCE EQUATIONS USED IN NORTH AMERICAN PULMONARY TRAINING CENTERS*

	FVC or VC M	FVC or VC F	FEV_1 M	FEV_1 F	FEV_1/FVC† M	FEV_1/FVC† F
Morris *et al.* (224)	65	65	65	65	58	60
Crapo *et al.* (91)	27	27	27	27	29	29
Knudson *et al.* (149)	24	24	25	25		
Kory *et al.* (153)	7		8			
Kory *et al.* (249)		7		8		
Cherniack *et al.* (225)	3	3	4	4		
Miller *et al.* (180)	2	2	2	2	2	2
Other studies‡	11	11	8	8	11	9

* Based on a questionnaire survey of adult respiratory disease training programs in the United States and Canada. Responses from 139 of 180 institutions are summarized (248).

† Thirty-nine centers predicted FEV_1/FVC by dividing predicted FEV_1 by predicted FVC.

‡ Studies cited only once.

TABLE 11

RESPONSE TO BRONCHODILATOR: RESULTS FROM SELECTED POPULATION STUDIES

Population	Agent/Mode of Delivery	FVC	FEV_1	$FEF_{25-75\%}$ or FEF_{50}	Comments
1,063 subjects 8–75 yr of age General population sample from Tucson, AZ (186)	Two inhalations of isoproterenol via metered-dose inhaler	10.7% (403 ml)	7.7% (315 ml)	20%	95th percentile for percentage change from baseline (absolute value in parentheses)
2,609 subjects; random sample of three areas in Alberta, Canada (187)	500 μg terbutaline administered via spacer	—	Females 9% (224 ml) Males 9% (338 ml)	—	95th percentile for percentage change from baseline in asymptomatic never smokers with FEV_1 > 80% predicted (absolute value in parentheses)
75 selected normal subjects (188)	Two inhalations from a Bronkometer™ metered-dose inhaler	5.1% (231 ml)	10.1% (365 ml)	48.3%	Upper 95% confidence limits (two-tailed) for percentage change from baseline
RESPONSE TO BRONCHODILATOR: RESULTS FROM SELECTED PATIENT STUDIES					
40 patients referred to pulmonary function lab (189)	Placebo	14.9% (340 ml)	12.3% (178 ml)	45.1%	Upper 95% confidence interval change after placebo inhalation. Absolute values in parentheses.
985 patients with COPD participating in the IPPB trial (190)	250 μg isoproterenol air compressor nebulizer	—	15%	—	Average increase as percent of initial FEV_1 (5% as percent of predicted normal FEV_1)
150 patients with airway obstruction (191)	200 μg salbutamol or 500 μg terbutaline via metered-dose inhaler	15% (330 ml)	10% (160 ml)	—	95% confidence interval for absolute change; absolute rather than relative change preferred measure of bronchodilator response

is no consensus on how a bronchodilator response should be expressed. The three most common methods are: percent of the initial spirometric value, percent of the initial predicted baseline value, and absolute change. Expressing the change in FEV_1 as a percent of predicted FEV_1 deserves further study as it has been reported to have advantages over current methods (193). When using the percent change from the initial values as the criterion, most authorities would require at least a 12 to 15% increase in FEV_1 from the baseline value as necessary to define a meaningful response. Increments of less than 8% (or of less than 150 ml) are likely to be within measurement variability (191, 192). One should interpret improvement in an individual subject only if the percent change and absolute change in FEV_1 or VC are clearly beyond the expected variability of the measurement during a single testing session. A patient may respond to long-term bronchodilator therapy even though a bronchodilator response is not seen in a single laboratory testing session.

The $FEF_{25-75\%}$ is a highly variable spirometric test, in part because of its dependence on FVC, which increases with expiratory time with obstruction. If FVC changes, postbronchodilator $FEF_{25-75\%}$ is not comparable with that measured prebronchodilator. Volume adjustment of $FEF_{25-75\%}$ has been used to deal with this issue (194, 195). At least two studies have assessed the utility of $FEF_{25-75\%}$. The results were disappointing, with only 8% of asthmatics (195) and 7% of patients with chronic obstructive pulmonary disease (COPD) (196) identified by $FEF_{25-75\%}$ criteria alone as outside the expected range. Tests such as the FEV_1/VC ratio and flow rates measured at some fraction of the VC may also be misleading in assessing bronchodilator response if expiratory time changes are not considered and if flows are not measured at the same volume below TLC.

Current published criteria and the Workshop recommendations for determining bronchodilator response are given in table 12.

Interpretation of Lung Function Tests in Clinical Practice

Pulmonary function tests may be used to address major issues in clinical case management. These include describing dysfunction and assessing its severity, explaining it in terms of diagnosis, establishing prognosis, planning management, and assessing trends over time, including changes after treatment. Pulmonary function tests may also be used to identify an abnormality in subjects without a known pulmonary disorder, as in preoperative assessments, in routine health status evaluations, and in clinical screening. Finally, pulmonary function tests are increasingly requested as part of health assessment on behalf of a third party (e.g., an insurance company or a governmental agency) where the clinician is not in his or her usual patient advocacy role and the subject or patient is, consequently, wary. In each of these situations, the question asked of the pulmonary function laboratory is quite different. Ideally, interpretations of pulmonary function tests should depend on the purpose of the tests and, when performed on patients with known disease, should be oriented to answering the specific question of the clinician ordering the procedure. Tests interpreted without clinical information will be limited in their clinical utility and the interpretation will usually represent only a refined description of the data obtained.

The first step in interpreting a lung function test is to evaluate the quality of the study. If there are reasons to suspect the quality of the test, avoid specific diagnostic statements. Dysfunction discovered under these circumstances should indicate only the need for more definitive testing.

TABLE 12

RECOMMENDED CRITERIA FOR RESPONSE TO A BRONCHODILATOR IN ADULTS

Organization	FVC (%)	FEV_1 (%)	$FEF_{25-75\%}$ (%)	Comments
American College of Chest Physicians (197)	15–25	15–25	15–25	% of baseline in at least two of three tests
Intermountain Thoracic Society (19)	15	12	45	% of baseline
ATS (current document)	12	12		% of baseline and an absolute change of 200 ml

Patterns of Dysfunction

Certain patterns of physiologic abnormalities can be recognized, and although they are seldom if ever pathognomonic for a specific disease entity, the types of clinical illnesses most likely to produce the observed set of physiologic disturbances can be pointed out. Regardless of the extent of testing, the most important point with regard to pattern recognition is the need to be conservative with respect to suggesting a specific diagnosis for the underlying disease process based only on pulmonary function abnormalities. Recognition of characteristic patterns of dysfunction depends a great deal the comprehensiveness of the lung function evaluation. However, even with only spirometric results, one can determine whether the pattern is compatible with obstruction with or without a reduction in VC. A reduced VC without evidence of expiratory slowing is a nonspecific finding. There was controversy among Workshop participants about using the term "restrictive" when VC is low. The majority thought it was acceptable to interpret the finding as indicating a "restrictive type of ventilatory impairment," or a "restrictive ventilatory defect" while recognizing that it does not necessarily indicate restrictive lung disease. Others argued the interpretation should be descriptive only, i.e., simply noted as "reduced vital capacity" or "nonobstructive defect," and call for further testing, including lung volumes, to clarify its nature.

The VC, FEV_1, and FEV_1/VC ratio are the basic parameters used to interpret spirometry. Although FVC is often used in place of VC it is preferable to use the largest VC, whether obtained on inspiration (IVC), slow expiration (EVC), or forced expiration (FVC), for clinical testing. The FVC is usually reduced more than IVC or EVC in airflow obstruction. Limiting primary interpretation of spirograms to three variables avoids the problem of simultaneously examining a multitude of measurements to see if any abnormalities are present, a procedure that will lead to an inordinate number of "abnormal" tests among the healthiest groups in a population (198, 199). Even when the rate of abnormality for any single test is only 5%, the frequency of at least one abnormal test was shown to be 10% in 251 healthy subjects when FEV_1, FVC, and FEV_1/FVC ratio were examined and increased to 24% when a battery of 14 different measurements were analyzed (198).

The FEV_1/VC ratio is the most important measurement for distinguishing an obstructive impairment. Expiratory flow measurements other than the FEV_1 and FEV_1/VC should be considered only after determining the presence and clinical severity of obstructive impairment using the basic values mentioned above. When FEV_1 and the FEV_1/VC ratio are within the expected range, abnormalities in flow occurring late in the maximal expiratory flow-volume (MEFV) curve should not be graded as to severity, and, if mentioned, interpretation of their clinical significance should be guarded. In the presence of a borderline value for FEV_1/FVC, however, they may help confirm the presence of airway obstruction. The same is true for average flows such as $FEF_{25-75\%}$. Even when used in this limited way, the wide variability of these tests in healthy subjects must be taken into account in their interpretation.

One should be cautious in interpreting obstructive dysfunction when the FEV_1 and VC are both above predicted even when the FEV_1/VC ratio is below the lower limit of normal since this pattern is sometimes seen in healthy subjects, including athletes. Tests other than spirometry, including lung volumes, diffusing capacity, and blood gas determinations allow amplifying statements on the overall pattern of the dysfunction observed during spirometry.

Lower Limits of "Normal" in Clinical Interpretation

Lower limits of normal are often used in clinical practice without thoughtful reflection about their inherent variability (5, 180, 181, 200–207) or their implications (5, 182). (See also sections Distribution and Lower Limits of Normal, Determination of the Normal Range, and Conceptual Issues Concerning Normality and the Limits of Normal.) Although clinical interpretation is usually straightforward when a pulmonary function result is well above or below a "lower limit of normal," this is not so when a measured value falls close to the "lower limit of normal." Predicting the presence or absence of disease requires knowledge about the distribution of dysfunction in various disease states and the prior probability of disease. For example, consider the meaning of a spirometric study that shows FEV_1 values and other expiratory flow rates to be just above the lower limit of normal. If the patient were a healthy male who sought medical assistance because he was disqualified for life insurance on the basis of his spirometry, it would be appropriate to interpret his spirometry as within normal limits. If, in contrast, the same data were obtained from a smoker with complaints of intermittent coughing and occasional wheezing, it would be appropriate to suggest that the study is consistent with mild obstructive dysfunction, although it could also represent a variant of normal. In both of these instances, computer printouts, or robotic physician interpretation that simplistically declare the results to be "normal" or "abnormal" on the basis of whether the observed values fall to one side or the other of a single number, could give information that does not perform a useful service to the patient. One suggestion for minimizing the problems of overly simplistic use of the lower limits of "normal" in the interpretation of lung function tests is use of terms such as "unusually low" rather than "abnormal" for tests close to the lower limit of normal.

Assessing Severity

Severity scores are most appropriately derived from studies that relate pulmonary function test values to independent indices of performance such as ability to work and function in daily life, morbidity, and prognosis (208–212). For instance, in general, ability to work and to function in daily life relates to one's pulmonary function level. FVC and/or FEV_1, which also relate to maximal $\dot{V}O_2$ and work effort, are used in several published systems to rate impairment (208, 209). Pulmonary function level is also associated with morbidity; those with lower function having more respiratory complaints (212). Lung function level is also associated with prognosis, including a fatal outcome from heart as well as lung disease (213, 214) even in patients who have never smoked (215). In the Framingham study, vital capacity was a major independent predictor of cardiovascular morbidity and mortality (213, 214). In several occupational cohorts FEV_1 and FEV_1/FVC were independent predictors of all cause or respiratory disease mortality (216–218). In addition, a meta-analysis of mortality in six surveys in various U.K. working populations showed that the risk of dying of COPD was related to FEV_1 level. In comparison to those whose FEV_1 at initial examination was within 1 SD of average, those whose FEV_1 was more than 2 SD below average were 12 times more likely to die of COPD, over 10 times more likely to die of non-neoplastic respiratory disease, and more than twice as likely to die of vascular disease over a 20-yr follow-up period (219). A reduced FEV_1 also carries a 4- to 5-fold excess risk of lung cancer mortality (adjusted for cigarette smoking) (220, 221). Although there is good evidence that FEV_1 correlates with the severity of symptoms and prognosis in many circumstances (208, 211, 212, 219), the correlations do not allow one to accurately predict symptoms or prognosis for individual patients.

In clinical practice, predicted values are also used to grade severity. The severity of the spirometric abnormality is usually based on the actual or percent predicted FEV_1 in the case of obstructive disorders or on VC in nonobstructive disorders. An example of an algorithm sometimes employed for grading severity when nothing is known about the clinical question being asked is shown in table 13. It is intended only as an example and not as a standard. Its approach is based as much on clinical impression as on objective data. Although clinical experience has always played a major role in assessing severity, it can be enhanced by more exact methods, and physicians should probably view arbitrary severity scoring systems with caution.

Comments on the severity or significance of any abnormality depend on the circumstances under which a test is obtained. For example the assessment of severity of obstruction illustrated in table 13 may be relevant to COPD, but it would not be applicable to a patient with tracheal stenosis whose obstruction could be life-threatening and yet classified as only mildly reduced by this scheme.

The VC has some relationship to the extent of loss of functioning lung parenchyma

TABLE 13

EXAMPLE OF CRITERIA FOR ASSESSING THE SEVERITY OF ABNORMALITIES*

A. Normal: The test is interpreted as "within normal limits" if both the VC and the FEV_1/VC ratio are in the normal range.

B. Obstructive abnormality: This is interpreted when the FEV_1/VC ratio is below the normal range. The severity of the abnormality might be graded as follows:

"May be a physiological variant"	% Pred $FEV_1 \geq 100$
"Mild"	% Pred $FEV_1 < 100$ and ≥ 70
"Moderate"	% Pred $FEV_1 < 70$ and ≥ 60
"Moderately severe"	% Pred $FEV_1 < 60$ and ≥ 50
"Severe"	% Pred $FEV_1 < 50$ and ≥ 34
"Very severe"	% Pred $FEV_1 < 34$

C. Restrictive abnormality: This is most reliably interpreted on the basis of TLC. If this is not available, one may interpret a reduction in the VC without a reduction of the FEV_1/VC ratio as a "restriction of the volume excursion of the lung." The severity of the abnormality might be graded as follows:

Based on the TLC	
"Mild"	% Pred TLC < LLN but ≥ 70
"Moderate"	% Pred TLC < 70 and ≥ 60
"Moderately severe"	% Pred TLC < 60
Based on spirometry	
"Mild"	% Pred VC < LLN but ≥ 70
"Moderate"	% Pred VC < 70 and ≥ 60
"Moderately severe"	% Pred VC < 60 and ≥ 50
"Severe"	% Pred VC < 50 and ≥ 34
"Very severe"	% Pred VC < 34

Definition of abbreviation: LLN = lower limit of normal.

* This schema was contributed by Burrows and Lebowitz. It has been in use in the lung function laboratory at the Health Sciences Center in Tucson, Arizona for clinical purposes. It is intended only as an *example* of a transparent schema for assessing severity. Other schema may be acceptable as well. More work is required before any schema can be adopted as a standard. Note: All statements regarding severity should be accompanied by a disclaimer such as "as assessed by spirometry" or "physiologic assessments of severity may differ from clinical assessments."

TABLE 14

CHANGE IN SPIROMETRIC INDICES OVER TIME

	Percent Changes Required to be Significant		
	FVC	FEV_1	FEF_{25-75}
Within a day (222)			
Normal subjects	≥ 5	≥ 5	≥ 13
Patients with COPD	≥ 11	≥ 13	≥ 23
Week to week (222)			
Normal subjects	≥ 11	≥ 12	≥ 21
Patients with COPD	≥ 20	≥ 20	≥ 30
Year to year (69)	≥ 15	≥ 15	

in many nonobstructive lung disorders. It is also of some use in assessing respiratory muscle involvement in certain neuromuscular diseases. Here again, however, the VC may be only slightly impaired in diffuse interstitial diseases of sufficient severity to lead to marked loss of diffusing capacity and severe blood gas abnormalities, and a relatively small decrement in VC may indicate the onset of a severe respiratory problem in patients with a rapidly progressive neuromuscular disease.

The FEV_1/VC ratio should not be used in isolation to determine the severity of an obstructive disorder. Both the FEV_1 and VC may decline with progression of disease, and an FEV_1/VC of 0.5/1.0 indicates more impairment than one of 2.0/4.0, though both yield a ratio of 50%. Systems that use FEV_t/FVC to grade the severity of obstruction must deal with the effect of total expiratory time on FVC and FEV_1/FVC (19).

Changes in Spirometry over Time

Reliance should be placed on FEV_1 and VC for examining changes over time as they are the only spirometric variables that will consistently and correctly reflect the direction of the change in overall ventilatory function. Even using these simple tests, it is never easy to determine whether a change is "real" or only a result of test variability. All lung function measurements tend to be more variable when made weeks to months apart than when repeated at the same test session or even daily (222, 223). Changes should therefore be interpreted cautiously. It is more likely that a real change has occurred when there are a series of tests that show a consistent trend. As shown in table 14 significant changes, whether statistical or biologic, vary by parameter, time period, and the type of patient. For FVC and VC in healthy subjects, within-day change of 5% or more, between-weeks changes of 11 to 12% or more, and yearly change of 15% or more were generally thought by the Workshop to be clinically important.

The clinician seeing the patient can often interpret results of serial tests in a useful manner, not reproducible by any simple algorithm. For example, seemingly stable tests may prove very reassuring in a patient receiving therapy for a disease that is otherwise rapidly progressive. The same tests may be very disappointing if one is treating a disorder that is expected to improve dramatically with the therapy prescribed. Depending on the clinical situation, statistically insignificant trends in function may be very meaningful to the clinician. The greatest errors occur when one attempts to interpret serial changes in subjects without disease because test variability will usually far exceed the true annual decline, and reliable rates of change for an individual subject cannot be calculated without prolonged follow-up (69). Thus, in subjects with "normal" lung function, changes in VC or FEV_1 over 1 yr should probably exceed 15% (table 14) before any confidence can be given to the opinion that a meaningful year-to-year change has occurred.

Recommendations

Overall

Technical Issues

Although technical sources of variation in spirometry have been fully dealt with in other documents, it was considered important to reemphasize their key role, particularly in relation to the following points.

1. Laboratory directors should be constantly on guard to maintain the precision and accuracy of the measurements made in their laboratories and should be aware of the potential sources of technical variation. Quality control includes strict adherence to ATS guidelines for equipment performance and calibration.
2. Attention should be given to the spirometer temperature where the tests are performed. Temperature-related errors will be reduced when the spirometer temperature is between 17° and 40° C.
3. Computer calculations should be validated at the time equipment is purchased and after any changes are made in software or hardware.

Biologic Variation and Statistical Issues

1. Laboratory directors should be aware of the biologic sources of within- and between-individual variation in order to optimize the application of lung function tests to a particular patient. A number of within-individual sources of variation fall within the domain and control of the laboratory, whereas between-individual sources of variation are important in selecting appropriate reference values.
2. Environmental sources of variation pertinent to a given patient are more likely to be known to the referring clinician than to

the laboratory director and should be used in evaluating the clinical pertinence of a given lung function report. Laboratory directors should request this information from clinicians.

3. Those who generate and report lung function tests should be aware of the strengths and weaknesses of the statistical techniques used to generate the prediction values used for interpretation. Laboratory directors and chest physicians should also be aware of the strengths and limitations of the statistical concepts of normality.

Selecting Reference Values

General Considerations

1. Because of unexplained differences between published reference values, no one set of reference values is likely to be applicable to all laboratories and all clientele under all circumstances. The choice of reference values should be a matter of careful consideration by laboratory directors. It should not be left to the judgment of manufacturers of automated equipment.
2. Laboratories should indicate the source of reference values on their reports.
3. Ideally, reference values should be based on data obtained using equipment and procedures that conform to current ATS recommendations. The prediction equations listed in tables 3 and 4 and published since 1981 conform to current ATS recommendations.

Epidemiologic Considerations

1. Reference values should not come from studies based on hospital patients.
2. Reference values for most clinical applications should be based on cross-sectional studies.
3. Subjects used to generate reference values should be free of respiratory symptoms and disease. It is preferable to choose reference values for men and women from the same population source.
4. Reference equations based on nonsmokers should be used for most clinical applications. The problems in making adjustments for the biologic effects of smoking lead to the recommendation that such adjustments should not be part of routine clinical interpretation. Such adjustments may, occasionally, be made to address specific questions.
5. Altitude may be important in the selection of reference values for flow rates and D_{LCO}.

Statistical Considerations

1. Prediction equations for adults should include age and height as independent variables. Usually, separate equations are used for men and women.
2. Linear equations perform adequately for adults though they may overpredict in young adults and underpredict in the elderly.
3. Prediction equations should come from studies that present lower limits of normal or present information from which such lower limits can be calculated.
4. Reference equations should, in general, not be extrapolated for ages or heights beyond those covered by the data that generated them. If, for example, one calculates a predicted FEV_1 for an 85-yr-old person from prediction equations based on a population younger than 65 yr of age, the report should contain a cautionary statement.
5. The choice of reference values should consider the ethnic origins of the clientele of the laboratory. Although it is preferable to use equations based on the ethnic origins of the subject being tested, this is not always possible or practical. For instance, if a laboratory only occasionally serves subjects of a particular ethnic group, it is acceptable to adjust for ethnic differences by using a scaling factor as suggested in table 9.

Lower Limits of Normal

1. Normal ranges should be based on calculated fifth percentiles. Estimates of fifth percentiles based on the SEE are acceptable for indices with distributions that are close to Gaussian.
2. Lower limits of normal are variable and, therefore, should not be considered as arbitrary limits that correctly classify all patients into normal and abnormal groups. Patient values that lie close to lower limits should be interpreted with caution.
3. The use of 80% of predicted for a lower limit of normal for adult pulmonary function parameters is not recommended. This criterion works only for average persons and for a limited number of parameters. It creates major errors when applied to $FEF_{25-75\%}$ and the instantaneous flows. Fixed percent of predicted values may be acceptable in children.
4. In adults, it is not acceptable to used a fixed FEV_1/FVC ratio as a lower limit of normal.

Other Considerations

1. It is preferable for North American laboratories to select reference value studies based on North American populations and European laboratories studies based on European populations because an important portion of the variation between population studies remains unexplained.
2. To assist in the choice of reference values, it may be useful to make an empirical assessment of how different equations relate to measurements made in 20 to 40 healthy subjects typical of the laboratory's clientele. If the distribution of these measurements is, on the whole, within the range predicted, the choice is probably suitable. If this is not the case, the differences may be due to the laboratory (apparatus, technician, procedure) or it may be that the reference values are inappropriate for the laboratory's clientele. Both possibilities should be considered.

Recommendations for Interpretation

Overall Clinical Interpretation

1. Because interpretation of the lung function tests of an individual patient is best made in light of the clinical question asked of the tests, the clinician requesting the test should frame this question as precisely as possible. Likewise, the laboratory director responsible for seeing that the tests are carried out should insist that the clinical question be included in the requisition.
2. Interpreters of lung function tests should be conservative in suggesting a specific diagnosis based only on pulmonary function abnormalities.
3. Borderline "normal" values should be interpreted with caution. Such interpretations should, when possible, use clinical information in the decisions as to what is normal and what is abnormal.
4. The first step in interpretation is to evaluate and comment on the quality of the tests.
5. The number of test indices (e.g., FVC, FEV_1, etc.) used in interpretation should be limited to avoid an excessive number of false positive results.
6. The primary guides for spirometry interpretation should be VC (slow or forced), FEV_1, and FEV_1/VC.
7. Tests performed on children are best interpreted by those familar with pulmonary function in children.

Concerning Airway Obstruction

1. FEV_1/VC should be the primary guide for distinguishing obstructive from nonobstructive patterns.
2. Instantaneous and mid flows may be used to confirm the presence of airway obstruction in the presence of a borderline FEV_1/VC.
3. $FEF_{25-75\%}$ and the instantaneous flows should not be used to diagnose small airway disease in individual patients.
4. The pattern of a low FEV_1/VC ratio and greater than average VC and FEV_1 should be recognized as one that may occur in healthy individuals.
5. The severity of airway obstruction should be based on FEV_1 rather than FEV_1/VC.
6. Abnormalities in instantaneous flows and $FEF_{25-75\%}$ should not be graded as to severity when FEV_1 and FEV_1/VC are within the normal range.

Concerning Bronchodilator Response

1. VC (forced or slow) and FEV_1 should be the primary indices used to judge bronchodilator response. Total expiratory time should be considered when using FVC to assess bronchodilator response since FVC increases in obstructed patients as expiratory time increases.
2. A 12% increase, calculated from the prebronchodilator value, *and* a 200-ml increase in either FVC or FEV_1 are reasonable criteria for a positive bronchodilator response in adults.
3. $FEF_{25-75\%}$ and the instantaneous flows should be considered secondarily in evaluating bronchodilator response. If used, they must be volume-adjusted or the effect or changing FVC must be dealt with in the interpretation.
4. Ratios such as FEV_1/VC should not be used to judge bronchodilator response.

5. Patients may respond to bronchodilator therapy even though a bronchodilator response is absent in a laboratory test.

CONCERNING RESTRICTION

1. The diagnosis of a restrictive lung abnormality is based on a reduced TLC. A reduced VC in the presence of a normal FEV_1/VC may be used to suggest but not diagnose the presence of restriction.
2. The severity of restriction should be based on TLC. If VC is used to infer the presence of restriction, severity may be based on VC.

This Statement was prepared by the participants of a Workshop on Lung Function Testing: Selection of Reference Values and Interpretative Strategies. The workshop participants were: MARGARET BECKLAKE, M.D., and ROBERT O. CRAPO, M.D., *Co-Chairpersons*, A. SONIA BUIST, M.D., BENJAMIN BURROWS, M.D., JACK L. CLAUSEN, M.D., ALLAN L. COATES, M.D., JOHN COTES, D.M., DOUGLAS W. DOCKERY, PH.D., REED M. GARDNER, PH.D., JOHN L. HANKINSON, PH.D., JAMES HANLEY, PH.D., ROBERT L. JOHNSON, JR., M.D., MICHAEL D. LEBOWITZ, PH.D., PAOLO PAOLETTI, M.D., RENE PESLIN, M.D., GEORGE POLGAR, M.D., PHILIP H. QUANJER, M.D., MELVYN S. TOCKMAN, M.D., SCOTT T. WEISS, M.D., M.S., MARY ELLEN B. WOHL, M.D.

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THE DIAGNOSIS OF NONMALIGNANT DISEASES RELATED TO ASBESTOS

THIS OFFICIAL STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS ADOPTED BY THE ATS BOARD OF DIRECTORS, MARCH 1986.

Objective

The health effects of asbestos have become a cause of serious concern in recent years. It has been estimated that from 1940 to 1979, in the United States alone, 27,500,000 individuals were exposed to this mineral at work. Recognition of the diseases caused by asbestos exposure has led manufacturers to reduce exposure in a variety of ways, such as by using alternative materials and by instituting improved work practices. It has also led to widespread public concern over the presence of asbestos in the environment, and fear on the part of persons with minimal exposure. This and projections of future asbestos related illness have posed important public policy questions—whether to remove all asbestos in public buildings and what to do about the enormous estimated legal liability. In this context, physicians are commonly asked for advice. Furthermore, they are also consulted regarding the diagnosis of an asbestos-related respiratory condition in an exposed individual. While abundant literature exists on the health effects of asbestos, there is much that is conflicting. Accordingly, this report has been prepared by a group of experts to present an authoritative consensus view of the current state of knowledge while pointing out areas where additional information is necessary. An attempt is made to summarize our present knowledge on the diagnosis of nonmalignant asbestos-related pulmonary disease and provide the sources on which the opinion is based.

Reprints may be requested from your state or local Lung Association.

Asbestos—the Mineral

The generic term "asbestos" is used to describe a group of minerals which, when crushed, break into fibers rather than dust. They are hydrated fibrous silicates which have great tensile strength, heat resistance, acid resistance, and some varieties are also flexible. This weavable rock has numerous important uses in an industrial society, and world production and use climbed steadily since its commercial introduction in the late 19th century. Geology, mineralogy, and uses have been well described elsewhere (1, 2). World production of asbestos has dropped markedly since the mid 1970's. The cumulative production of asbestos, however, continues to increase. There has been a good deal of debate about the mineralogic definitions of asbestos and asbestiform fibers. The most complete recent discussion on trends in asbestos production and now widely accepted mineralogic definitions are found in the NAS Report on asbestiform fibers (3).

Asbestos in Lung Tissue

Inhaled asbestos that is retained in the lung can become coated with a proteinaceous iron staining material. The resulting asbestos or ferruginous body is a most characteristic index of asbestos exposure. It is usually recognized by its beaded-necklace or drumstick appearance. The longer fibers are more likely to become coated (2–22). The core of asbestos, i.e., bodies found in human lungs, is more likely to be an amphibole fiber than to be chrysotile, perhaps due to the greater ability of the former to survive in lung tissue, while chrysotile tends to disappear over time. The majority of the lung burden of asbestos, however, is uncoated and consists of short fibers, i.e., less than 5 microns (2–21). These are poorly visible or invisible on light microscopy but have been demonstrated by phase microscopy and electron microscopy. Asbestos bodies are commonly found in small numbers in lungs of city dwellers at routine autopsies in the absence of occupational exposure to asbestos and asbestos related illness. These are usually few in number and unassociated with pathologic abnormality in the parenchyma. This observation emphasizes the importance of developing standardized techniques to quantify the number and type of asbestos fibers in lung tissue (to be discussed below).

Benign Pleural Abnormalities Associated with Asbestos

Asbestos causes pleural plaques, pleural thickening and pleural effusion. Pleural plaques are discrete, elevated, opaque, shiny, rounded lesions. They characteristically occur on the posterolateral aspect of the lower parietal pleura or diaphragm, but usually not on the visceral pleura, at the costophrenic angles, or at the apices. Thin plaques are smooth and grayish-white. Thicker ones are ivory-colored or gray and may have either a smooth surface or bosselated surface, or be coarsely nodular with the consistency of cartilage. Plaques are of two types, diffuse or nodular, and elevated. They can vary in size and shape. On inspection of gross specimens, calcification may be present but is not common. Microscopically, plaques are seen to be laminated collagenous connective tissue, acellular, with few inflammatory or fibrocytic nuclei; many are covered by a thin layer of regular and well-differentiated mesothelial cells. Capillaries are rare (23, 24). Elastic staining shows intact lamellae beneath the plaque in continuity with the surrounding normal parietal pleural connective tissue, suggesting that plaques are extrapleural and develop between the latter and its covering layer of mesothelial cells (23). On microscopic examination, calcium deposition is present in a large proportion of plaques, and occurs as deposits along the course of the collagen fibers, ceasing abruptly where the connective tissue changes into normal pleural tissue (23). Well-differentiated cuboidal mesothelial cells are present on the surface and the edges of the plaque (23); metaplastic changes are uncommon (24, 25).

Although coated asbestos fibers have not been reported in relation to pleural plaques in the extensive series of 172 sections examined by Meurman (23) using polarized light, the presence of many uncoated fibers may be noted when ashed tissue is studied (26, 27). Recent studies of the digestate of a small number of plaques has demonstrated the presence of submicroscopic fibers of both chrysotile and amosite fiber in these structures. It is of interest that these are more concentrated in the calcified zones than in the fibrous zones (28).

The usual effect of asbestos on the visceral pleura is a focal or diffuse thickening. This varies from a thin, milky white discoloration, detectable only on gross visualization to a thick peel encasing the lung and easily seen on chest roentgenogram. In contrast to plaques, which are frequently diagnosed roentgenologically in asymptomatic persons, pleural fibrosis may cause symptoms and impair pulmonary function.

Pleural effusion may be caused by inhalation of asbestos; this is an early manifestation and is usually an exudate. On rare occasions it may persist for months or years. It may recur on the same or the opposite side after several years of exposure. In unusual circumstances it may be bilateral. Macroscopically, the fluid may be blood stained with variable numbers of erythrocytes, macrophages, lymphocytes, and mesothelial cells (29).

Pulmonary Asbestosis

Definition

The term asbestosis should be reserved for the interstitial fibrosis of the pulmonary parenchyma in which asbestos bodies or fibers may be demonstrated. While pleural abnormalities are commonly associated with parenchymal disease, they should be separately classified as there are differences between pleural and parenchymal fibrosis in epidemiology, clinical features, and prognosis.

Pathologic Features

In lungs with minimal or moderate fibrosis, changes may be subtle and difficult to demonstrate. On examination of gross specimens, they appear as gray opaque areas devoid of air spaces in an otherwise brown lung. The microscopic changes in pulmonary asbestosis vary from small areas of basal fibrosis to a diffuse, fine fibrosis of both lungs. In general, the more extensive the process the smaller the volume of the lungs. The cut surface of the lung has a dark brown color with streaks of a fine, gray-colored fibrosis that generally appears to affect subpleural areas first and, frequently, in multiple and separate areas. This fibrosis may accentuate lobar and lobular septa and extends projections into the lung parenchyma. The parenchymal fibrosis, which has a linear and reticular appearance by X-ray, affects the lower lobes first, and extends upward with prolonged or heavy exposure (10, 30, 31). The fibrosis may take one of three forms. One is a diffuse fibrosis without air space enlargement; a second form is called honeycombing. This form may affect the lower lobes and subpleural regions (31). The third form is a combination of both diffuse fibrosis and honeycombing. This latter form is the one most frequently observed. The honeycombing is characterized by enlarged thick-walled air spaces ranging in size from 1 to 15 mm (32). The pleural surface adjacent to the fibrosis is invariably involved in the fibrotic process, either mildly with the appearance of a milky covering to the fibrosis, or with widespread fibrosis and symphysis (30, 31). The hilar lymph nodes are only slightly enlarged and soft unless other disease coexists. While emphysema has been reported in the past, it is unusual, and may have been incorrectly labelled as honeycombing (10, 33).

Microscopic Appearances

There is little information on the early pathophysiology of asbestosis in humans. Current opinion is largely based on inferences from animal studies. Some evidence exists that release of lysosomal enzymes may result from the partial ingestion of the asbestos fibers and the incomplete fusions of the phagosome membrane, so allowing the release of enzymes into the medium from lysosomes which have fused with the phagosome. The cytotoxic activity of asbestos exhibited by the release of lysosomal enzymes may result from the fibers penetrating intracellular structures, such as the nucleus and lysosomes, by preventing the movement of organelles within the cytoplasm, or by disrupting the cytoplasmic organization provided by microfilaments and microtubules (34). In any case, the initial reaction to asbestos fiber introduced into the lung is the immediate exudation of neutrophils and macrophages into the alveolar spaces in the locus of asbestos. This exudate varies with the age of the lesion. In the initial stages the exudate may be predominantly neutrophilic. Macrophages are the most common cells in the infiltrate. The inflammatory infiltrate soon is associated with varying degrees of organization with fibrosis (35, 36). The process is believed to be concentrated initially in peribronchiolar regions (10, 30). The initial lesion after exposure by inhalation is in the region of the respiratory or terminal bronchioles. There is a macrophage exudate in the lumen associated with asbestos fibers and bodies. Metaplasia of the cuboidal epithelium to squamous type may occur. In the early stages, fibrosis may be minimal but, when present, is in the respiratory and terminal bronchiolar regions and in the alveoli arising from the most proximal alveolar ducts. Alternatively, there may be coboidalization of the epithelial cells. Characteristically, in early stages only an occasional pulmonary subunit is involved. More advanced cases show a diffuse fibrosis, involving the interstitium, frequently associated with areas of extensive fibrosis with obliteration of air spaces and condensation of the bronchovascular structures. Areas adjacent to the fibrosis may show accumulation of alveolar macrophages, some of which have ingested asbestos fibers or other fragments. Alveolar epithelial hyperplasia may also occur. When moderate or severe degrees of fibrosis are present, the small pulmonary arteries and arterioles are thickened and sclerotic (30). (The presence of uncoated asbestos fibers and asbestos bodies in the presence of interstitial fibrosis is mandatory for the pathologic diagnosis of asbestosis.)

Before a pathologic diagnosis of asbestosis can be made we must consider a number of problems, including the following:

1. There are numerous other causes of interstitial fibrosis.
2. The distribution of interstitial fibrosis in asbestosis may be irregular, and therefore, adequate sampling of the lung must be done. The lingula and the right middle lobe are particularly prone to nonspecific fibrosis and sampling must take this into consideration.
3. While advanced asbestosis characteristically shows numerous asbestos bodies, they may not always be found because many fibers are cleared from the lungs and some, particularly chrysotile, may undergo dissolution and fragmentation with time (32). Thus, in unusual cases it may be difficult to demonstrate fibers or asbestos bodies in the histologic preparation. When that is the case, 5 to 10 additional sections from the same block, and 5 to 10 additional new blocks from areas with fibrosis, should be prepared, stained, and surveyed for asbestos bodies. If they are not found, the diagnosis of asbestosis is unlikely.
4. Even in the absence of a history of asbestos exposure, the presence of several or more asbestos bodies in areas of extensive interstitial fibrosis is sufficient evidence for a morphologic diagnosis of asbestosis.
5. Not everyone who inhales an asbestos fiber, or even a few fibers, develops even microscopic asbestosis. Normal lung defense mechanisms remove fibers via several well-described mechanisms.

The Pneumoconiosis Committee of the American College of Pathologists and the National Institute for Occupational Safety and Health dealt with these considerations when formulating the following statement with which we concur:

> "The criteria that permit the pathologist to establish the diagnosis of asbestosis have evolved during a review of many cases of the disease. Presently, the minimal features that permit the

diagnosis are the demonstration of discrete foci of fibrosis in the walls of respiratory bronchioles associated with accumulations of asbestos bodies. These morphologic findings, although adequate to establish the diagnosis of asbestosis in an early evolutionary stage, have not been shown to result in functional and radiologic alterations. The demonstration of asbestos bodies in the absence of fibrosis is insufficient evidence to justify the diagnosis of asbestosis. Conversely, a definite diagnosis of asbestosis cannot be made by the pathologist in cases that show characteristic fibrosis in the absence of asbestos bodies or other evidence of fibers. Because asbestos bodies are unevenly distributed in tissue, an adequate number of samples should be examined thoroughly." (32)

They further state that although the demonstration of asbestos fibers by the electron microscopic study of tissue digestates provides evidence of exposure, ultrastructural technique alone cannot be used to establish definitively the etiologic role of asbestos in disease (32).

This Committee has published guidelines for methods of assessing lung fiber concentration and pathologic grading of asbestosis. The certainty of the cause and effect relationship of asbestos to the fibrotic process increases with increasing numbers of such particles and fibers visualized by light microscopy. Electron microscopy of digested lung preparation from documented cases of asbestosis shows very large numbers of uncoated fiber fragments (37).

Since asbestos bodies and fibers appear in lungs without evidence of asbestos-related disease, the question arises as to how many such bodies are necessary to infer a cause and effect relationship between asbestos particles and fibrosis. No precise answer exists, but efforts to quantify the numbers of asbestos particles in known cases indicate that it is high. In the cases of asbestosis studied by Whitwell, the lungs nearly always showed three million light visible fibers per gram; control lungs generally show less than 20,000 fibers per gram (38).

Electron microscopy is a more sensitive index of asbestos exposure than light microscopy. It will detect 10 to 100 times more fibers than seen by light microscopy. Fibers seen only by light or electron microscopy, in the absence of parenchymal fibrosis, indicates only that exposure to asbestos has occurred. Additional studies are required to define the number of fibers in the lungs of persons with a variety of occupational exposures, and with varying periods of exposure, as well as in nonoccupational populations.

Investigations have demonstrated that as many as a million fibers per gram of dry tissue of chrysotile may be present in the lungs from nonoccupational exposures in the general population. By contrast, lungs containing a million fibers of amosite or crocidolite per gram are considered to reflect substantial occupational exposure to asbestos dust (39). An electron microscopic field of necessity represents a small sample of the lung and analysis of multiple fields is required to reflect the true asbestos lung burden. In our opinion, additional studies on the numbers and types of asbestos fibers in the lungs of control and exposed persons must be performed to provide the informational bases for interpretation of quantitative data concerning asbestos fibers in the lung and their relation to the presence of asbestosis or other asbestos related diseases.

Exposure History

Numerous studies have shown that asbestosis has a relatively close association with both the magnitude and the duration of exposure to inhaled asbestos; the more intense and longer the exposure, the greater the numbers of affected workers and the greater the severity of their illness. There is no evidence that casual or indirect exposure, such as occurs in the general population, causes asbestosis. The major problem facing the clinician is to assess whether an exposure has been sufficient to cause disease. Although dust levels have been measured in many industries for many years, they are not usually available to or easily interpreted by clinicians. Nevertheless, some general statements can be made. A careful sequential history of all exposures to all potentially harmful substances is obviously important. Particular attention should be paid to occupations in which direct contact with asbestos has occurred. Consultation with physicians trained in occupational medicine or with industrial hygienists may be helpful in unclear cases.

Evidence of asbestosis has been found many years after relatively brief but extremely heavy exposure. Such exposure often occurred in the asbestos textile industry over 50 years ago and has occurred more recently in workers who have not used respiratory protection while spraying dry asbestos on steel beams. Fortunately, such exposure is rare at this time. With levels of exposure common in the past few decades, the latent period between the state of the exposure and the discovery of the manifestations of asbestosis is likely to be a minimum of 15 years, and more often considerably longer. With exposures below the current recommended permissible exposure limit value, asbestosis is not likely to be found during the course of a working career. With proper engineering controls, work practice, and where necessary, personal respiratory protective devices, asbestosis should not occur.

Clinical Diagnosis

In the usual clinical setting, the diagnosis of asbestosis has to be made in the absence of histologic examination of lung tissue. Open lung biopsy is rarely indicated in the assessment of workers for compensation purposes. The benefit of the doubt should be given whenever the clinical features and occupational exposure data are compatible with the diagnosis. In most instances, the clinician and epidemiologist must still rely on indirect methods of diagnosing asbestosis. These principles of diagnosis are based on observations from pathologically proven cases. When biopsy is done, careful attention must be paid to the sampling considerations mentioned above and the surgical technique employed (40). Assessment of lung dust burden in such biopsy material is desirable. Diagnosis of asbestosis does not mean that measurable impairment of lung function or physical disability is necessarily present.

Clinical Features

In advanced stages, asbestosis is a restrictive lung disease associated with dyspnea, clubbing of the fingers, basilar crackles and widespread irregular opacifications on roentgenograms. The latter are usually more prominent at the lung bases. Pleural thickening and calcification may also be present as noted above. The vital capacity is usually reduced with preservation of the FEV_1/FVC ratio and gas exchange impaired. Cor pulmonale may occur in advanced disease. When many or all of these features are present the diagnosis is made without difficulty. However, in the absence of the opportunity to examine lung tissue microscopically, the diagnosis is always inferential. The certainty increases with increasing numbers and severity of typical clinical abnormalities.

The chest roentgenogram appears to be the most valuable examination in diagnosing asbestosis. A diffuse irregular interstitial pattern coupled with evidence of pleural disease, e.g., plaques or extensive pleural thickening in a person with known exposure, presents little diagnostic difficulty. The difficulty with the use of the chest roentgenogram relates to the detection of lesser degrees of interstitial fibrosis. Efforts have been made to standardize the interpretation of roentgenograms in the pneumoconioses. The most widely accepted and extensively studied method for assessing the degree of roentgenologic involvement in the pneumoconioses was developed by the International Labour Office and is currently called the ILO-1980 Classification (41). This scheme evolved from studies of miners and focused initially on the detection of silicosis. The X-ray appearance of silicosis is characterized initially by small rounded opacifications. The classification was later broadened to describe abnormalities which occur in asbestosis and do not have a rounded appearance. These are fine, medium and coarse, small irregular opacifications, and they are called s, t, and u, respectively. The classification, originally developed for describing radiologic changes in epidemiologic studies, has also been used in the clinical context for case detection and/or diagnosis. In the latter instance, the information given in the chest radiograph is added to all other information about the individual in order to arrive at a diagnosis.

The number of these abnormalities in a given area of the chest film, whether rounded or irregular, is called their profusion. The profusion was initially graded as 0 for none, 1 for slight, 2 for moderate, and 3 for severe.

It became apparent, however, that even experienced readers had difficulty in grading opacifications into these categories in a reproducible fashion. However, if observers were asked to give two classifications, i.e., the one category they thought was most likely and another which they thought might also be considered, the observer reliability (i.e., in terms of reproducibility) was considerably improved. This method of giving the observer two options (the one he thought most likely and next most likely) was called the expanded classification. It formed a 12-point scale that has proven to be very useful epidemiologically.

It is likely that an individual who develops asbestosis moves more or less uniformly from the normal roentgenologic appearances (-/0, 0/0, 0/1) to the abnormal (1/2, 2/1, 2/2, etc.). The problem is that the interpretation of the lesser degrees of abnormality on this scale is subjective and that numerous causes of such roentgenologic shadowing other than asbestosis exist. In the presence of marked diffuse pleural thickening, it is difficult to diagnose or grade the severity of interstitial fibrosis. Accordingly, criteria other than roentgenographic ones have been sought.

Dyspnea

Asbestosis has been described as a monosymptomatic disease, dyspnea being the major complaint of the affected individual (42). There is no doubt that shortness of breath is common and troublesome in individuals with clinically significant interstitial fibrosis. Dyspnea, however, is a nonspecific symptom, common in many other cardiopulmonary disorders, and it is particularly subject to emotional factors likely to be relevant in instances of suspected industrially-related disease. Accordingly, it is not adequate to use dyspnea as the only evidence on which to base a clinical diagnosis of asbestosis in an individual at risk.

Clubbing

Clubbing of the fingers occurs more commonly in asbestos-exposed workers than in controls (43, 44, 45). The diagnostic usefulness of clubbing is limited, however, by two important considerations. There are many other causes of clubbing and clubbing, when present, is a late finding in pulmonary asbestosis (46). Since the majority of persons with significant asbestosis do not have clubbing, and asbestos workers with clubbing may have it for reasons other than pulmonary fibrosis, the diagnostic usefulness of clubbing is limited.

Basilar Crackles

Crackles have been recognized as a feature of asbestosis for over 50 years and are believed by many to be an early finding (47, 48, 49). They have been described as characteristic in their sound ("fine," "cellophane," "velcro," "close to the ear") and in their bilateral, basilar distribution (50). They differ in quality and timing from the crackles of bronchitis which tend to be fewer in number and earlier in timing. Bronchitic crackling begins with the beginning of inspiration and usually discontinues prior to mid or late inspiration. Characteristically, the crackles of interstitial fibrosis are pan inspiratory or have an end inspiratory accentuation. They appear first at the bases in the mid-axillary lines and tend to spread toward the posterior bases. As the disease advances, the crackles become distributed at progressively high levels up from the bases (50). They are often difficult to distinguish from the crackles of congestive heart failure. Reported rates vary, but about half of the persons considered to have asbestosis on clinical grounds have crackles (47, 51, 52, 53); prevalences in exposed populations range from about 10–20%. Such prevalences depend on duration of exposure, the age of the population, and prevalence of other diseases causing fine crackles. Observer variability exists in chest auscultation, but this can be reduced by training and waveform analysis (54, 55, 56). In summary, under carefully controlled circumstances crackles can be useful in diagnosing interstitial fibrosis. However, they are not also specific for the interstitial fibrosis related to asbestos.

Pulmonary Function

The characteristic features of pulmonary asbestosis are those of a restrictive lung disease, i.e., a reduction in lung volumes, with inspiratory capacity and vital capacity being primarily affected, functional residual capacity being less affected, and residual volume even less. These changes are consistent with a decrease in pulmonary compliance. Hypoxemia may be present at rest or develop with exercise. Diffusing capacity is also usually impaired, depending on the extent of the disease. By contrast, large airway function as reflected in the FEV_1/FVC ratio is generally well preserved. Review of the prediction formulas for pulmonary function tests reveals there is no one set applicable to all laboratories and patient populations. Predicted normal values used in pulmonary function laboratories should be based on regression equations from studies whose testing equipment, methodologies and control populations most clearly resemble the patients under study. Numerous studies have shown that the effects of asbestos on lung function are dose related (57, 58, 59).

There is convincing evidence that an asbestos related pulmonary abnormality can occur in the absence of definite radiologic change. These pathologic changes of early asbestosis have been demonstrated in biopsy material from asbestos-exposed individuals with minimal or no radiologic abnormality (60). Likewise, exposure response relationships for certain pulmonary function abnormalities (including reduced lung compliance and impaired flow at low lung volumes) have been demonstrated in asbestos-exposed subjects without radiologic abnormalities or reduction in vital capacity (58), and their occurrence subsequently confirmed in large animal models with biopsy confirmation of the associated pathologic changes. The impairment associated with such abnormality is usually modest.

Diffusing Capacity

Diffusing capacity or transfer factor has been the subject of numerous studies with somewhat conflicting results. In most studies of unexposed populations it is lower in asbestos exposed workers than in normal controls although not always at a statistically significant level (44, 45, 57, 62, 63). There is not always a clear relationship to dust exposure indices (58, 64). It has, however, been shown to correlate with the severity of the histologic lesion in interstitial fibrosis (64), and its reduction can precede roentgenologic abnormalities. At this time a reduction of the diffusing capacity in an asbestos worker, in the absence of other known causes for impaired gas exchange, would provide suggestive evidence for asbestosis, but further population studies are necessary to elucidate the precise role of this test.

Other Studies

Various other measurements have been employed for monitoring persons exposed to asbestos. A reduction in roentgenologic lung volume appears promising since it is applicable to serial studies of patients, but it requires careful control of inspiration (66). This approach has not yet been taken in a large number of subjects exposed to asbestos.

Inspiratory capacity was shown to be suitable for surveillance of workers but is not likely to add much more than vital capacity (VC) as the two tests are highly correlated (59). This finding suggests that tests for small airways disease might in the future be applicable to early detection (67). In one study, neither closing volume nor closing capacity correlated with the duration of exposure or with the asbestos dust index (68). Gallium scanning, bronchoalveolar lavage, and transbronchial biopsy need further evaluation with respect to their usefulness in diagnosing asbestosis. CT scanning is of particular value in detecting and quantitating pleural disease and aiding in the differentiation of pleural from parenchymal disease. The value of CT scanning in the detection of interstitial fibrosis also needs to be further evaluated. Thus, at this time, criteria other than crackles, restrictive lung functional abnormality, reduced diffusing capacity of the lung (D_L), and roentgenogram consistent with interstitial fibrosis of 1/1 or more are either impractical, of unproven value, or are not likely to yield additional information because of their high correlation with one of these four.

In our opinion, combinations of these abnormalities are more reliable in terms of specificity, relation to duration of exposure, consistency, and predictive value; however, little work has assessed combinations of abnormalities.

Combinations

Combinations of abnormal test results are not likely to prove more effective in detecting the earliest changes in asbestosis. Intuitively, one test is likely to become abnormal first. It is likely that the first abnormality is not always the same one (e.g., one worker may have only an abnormal DL [69], and another only crackles as the first manifestation). This has been demonstrated with respect to restrictive lung function pattern and reduced DL. It is likely that observations will have to be made in large groups over long periods to delineate clearly the best single test for early diagnosis of asbestosis if, indeed, a single initial abnormality exists.

Differential Diagnosis

Streaky densities on chest films consistent with a parenchymal disease have many causes. All alternative diagnoses must be considered before accepting the presumptive diagnosis of asbestosis.

Occasionally, asbestosis is coexistent with chronic obstructive pulmonary disease. Evidence is accumulating that obstruction may also be related to an individual's occupational exposure (70). The relative importance of cigarette smoking and asbestos in the development of the combined problem of restrictive and obstructive disease may be difficult or even impossible to assess.

Since a not uncommon feature of asbestos exposure is bilateral pleural thickening, the question arises as to the helpfulness of such thickening in indicating that a patient with pulmonary fibrosis has asbestosis. Indeed, asbestos appears to be a rather potent stimulus for the development of pleural abnormalities. Selikoff found pleural fibrosis in 65% of persons he studied 40 years from the onset of their initial exposure to asbestos. With patients with no known exposure to asbestos or other known hazardous materials (71), the question arises as to whether an indirect or occult exposure to asbestos might have caused the pleural thickening. Severe diffuse pleural thickening is not common even in asbestos exposure. It was present in only 2.5% of the asbestos workers studied by Selikoff. Since there were no controls in that study, it is difficult to be certain that asbestos was the cause of the pleural fibrosis in those subjects. Indeed, Gilson reported in 1969 that pleural thickening was found on 187 of 3,860 (0.05%) routine roentgenograms of the chest in Great Britain (72). He conducted one of the few objective studies of pleural thickening by comparing the asbestos exposure of 113 of the 187 subjects with that of 113 age- and sex-matched controls. He found "a slight but unimpressive excess of positive histories of exposure to asbestos among the cases." Thus, it is not necessary to assume an occult exposure to asbestos in every instance of pleural thickening; the presence of pleural thickening is not definitive evidence of asbestos exposure. In another study, bilateral pleural thickening was found in 52 of 824 consecutive patients admitted to the hospital. Only 13 of these 52 had definite asbestos exposure as compared to 2 of 32 age-matched controls. In contrast to the relatively nonspecific finding of pleural thickening, the demonstration of pleural plaques with or without calcification is better evidence of asbestos exposure. Unfortunately, the latter usually occurs only many years after the onset of the exposure, thus limiting usefulness of early diagnosis.

A major problem exists in the differential diagnosis when more than one disease is present, whether it is congestive heart failure, COPD, or other chronic lung disease. There are diseases unrelated to asbestos exposure but with similar symptoms, and these may occur in some persons with asbestos exposure. However, given a clear history of exposure to asbestos, a diffuse interstitial fibrosis can be presumed to be due to the asbestos as other forms of interstitial fibrosis are relatively uncommon. The prevalence of lesser degrees of interstitial fibrosis is not well known and considerable caution has to be exercised in attributing all such phenomena to asbestos exposure, either known or occult.

Summary

This document has focused on clinically detectable interstitial fibrosis due to asbestos exposure. While direct examination of lung tissue is the most reliable method of diagnosis, as stated above, this is rarely indicated in the assessment of workers for compensation purposes. Open lung biopsy is indicated in our opinion only when a clear health, rather than financial, benefit is likely to be provided. In the absence of pathologic examination of lung tissue, the diagnosis of asbestosis is a judgement based on a careful consideration of all relevant clinical findings. In our opinion, it is necessary that there be:

1. A reliable history of exposure.
2. An appropriate time interval between exposure and detection (see pages 9–10)

Furthermore, we regard the following clinical criteria to be of recognized value:

1. Chest roentgenographic evidence of type "s," "t," "u," small irregular opacifications of a profusion of 1/1 or greater
2. A restrictive pattern of lung impairment with a forced vital capacity below the lower limit of normal
3. A diffusing capacity below the lower limit of normal
4. Bilateral late or pan inspiratory crackles at the posterior lung bases not cleared by cough

Of these, the findings on the chest roentgenogram are the most important. When this criteria is not met, considerable caution is warranted. The specificity of the above criteria increases with increasing numbers of positive criteria. As in all clinical judgments, confounding variables, such as the presence of other clinical conditions that affect these criteria, should be evaluated.

It is possible that interstitial fibrosis may be present even though none of these criteria are satisfied, but, in our opinion, in these circumstances the clinical diagnosis cannot be made.

This statement was prepared by an Ad Hoc Committee of the Scientific Assembly on Environmental and Occupational Health in conjunction with the American College of Chest Physicians. The members of the Committee were:

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9

American Thoracic Society

MEDICAL SECTION OF THE AMERICAN LUNG ASSOCIATION

EVALUATION OF IMPAIRMENT/DISABILITY SECONDARY TO RESPIRATORY DISORDERS

THIS OFFICIAL ATS STATEMENT WAS ADOPTED BY THE ATS BOARD OF DIRECTORS, MARCH 1986.

Purpose

This Statement sets forth recommendations for determining the presence and degree of impairment caused by respiratory disease or by diseases of other systems that may have adverse effects on lung function. The intention is to provide standards for the determination of impairment. The classification of functional status is to be made from technically valid results of spirometric and diffusing capacity tests. Standard tests of ventilatory and gas transfer functions provide sufficient data for determining respiratory system impairment (or its absence) in the great majority of patients referred for such evaluation. It is expressly recognized that further testing, including exercise testing, may be helpful in selected cases.

Although mild reductions in respiratory function do not frequently limit exercise or work capacity, severe reductions can become a limiting factor even if other body systems have remained functionally intact. Because normal ventilatory and gas transfer capacities far exceed circulatory system limits on gas transport, substantial amounts of respiratory reserve must be lost before respiratory dysfunction imposes limitations on the multisystem response to the demands of exercising muscles.

This Statement is concerned primarily with impairments related to reduced lung function. Levels of pulmonary impairment have been defined which, with high probability, will produce a respiratory limitation on the ability to exercise or work. This approach involves decisions about placing points along the continuum of test results to define and distinguish among the unimpaired and the mildly, moderately, and severely impaired. Although such choices are inherently arbitrary, the usefulness of the rating system will ultimately depend on how well it permits accurate classification of levels of impairment; i.e., how well it serves to predict respiratory limitation of capacity for exertion. Barring large improvements in measurement technology or enormous increases in the resources for more sophisticated testing, there will continue to be a need to determine respiratory impairment using simple lung function tests.

Background

There are several rating schemes used for defining the degree of respiratory impairment (1–7). Some of these schemes are based on actual values of pulmonary function tests (1, 3, 4), while others use predicted values (6–8). One scheme is based on severe dyspnea (5). In 1978, the Component Committee for Disability Criteria of the American Lung Association reviewed these programs, along with other available information, in their efforts to develop impairment/disability criteria in respiratory disease that would standardize the assessment of respiratory impairment. The Committee's statement dealt only with severe impairment; i.e., impairment of such severity to preclude gainful employment and to cause total disability (9). This new Statement represents a revision and expansion to include less severe categories of impairment (partial disability) and other respiratory conditions not previously considered.

Impairment versus Disability

Impairment

This is purely a medical condition. Most impairments result from a functional abnormality, which may or may not be stable at the time the evaluation is made, and may be temporary or permanent. Those that persist after appropriate therapy with no reasonable prospect of improvement are permanent. Impairments of lung function may be of varying degrees of severity, ranging from those that preclude some types of labor to those that ordinarily preclude any gainful employment.

Some impairments are not dependent on lung function and result from an environmentally related diagnosis (e.g., occupational asthma warrants proscription of continuing exposure to the inciting agents), from the prognosis (e.g., unresectable lung cancer), or from public health considerations (e.g., tuberculosis).

Disability

A term that indicates the total effect of impairment on a patient's life. It is affected by such diverse factors as age, gender, education, economic and social environment, and energy requirements of the occupation.

Two people with an identical impairment may be differently affected in their life situations.

The rating of health impairment falls within the province of a physician's expertise to quantitate. Determination of disability is an administrative decision that requires consideration of many nonmedical as well as medical variables.

Medical Diagnosis

Accurate assessment of respiratory impairment requires a medical diagnostic evaluation. Reduced lung function may result totally or in part from nonrespiratory diseases either directly (e.g., arthritis of the spine, neuromuscular diseases) or indirectly (e.g., congestive heart failure). Moreover, accurate diagnosis is the basis for sound prognosis and medical proscriptions, which later may bear importantly on the determinations of impairment and of disability. In addition to indicated laboratory tests, the evaluation for respiratory diseases must include a chest radiograph at minimum.

Impairment Directly Related to Reduced Lung Function

Pulmonary Function Tests (Primary Tests)

The FEV_1, FVC, FEV_1/FVC, and $DL_{CO}sb$ are the primary tests recommended for the determination of respiratory impairment. Although this Statement is not concerned with the definition of normality, a widely accepted definition is the mean predicted value ± 20%.

FORCED SPIROMETRY MEASUREMENTS

Three measurements of pulmonary function are included in this step: FVC, FEV_1, and FEV_1/FVC%.

The subjects should be evaluated only after an accurate diagnosis and while receiving optimal therapy. If obstruction is present (FEV_1/FVC is below 0.75), the ventilatory studies should be repeated after the adminis-

Reprints may be requested from your state or local Lung Association.

TABLE 1

RECOMMENDED REGRESSION EQUATIONS FOR MEASUREMENT OF FEV_1

	Units	Equation
Males	L-BTPS	0.0414 H − 0.0244 A − 2.190
Females	L-BTPS	0.0342 H − 0.0255 A − 1.578

Definition of abbreviations: L-BTPS = liters at BTPS; H = height (cm); A = age (yr).

tration of an inhaled bronchodilator. If the patient is taking bronchodilators, the drugs and times of last doses should be recorded.

The equipment, methods of calibration, and technique used should meet the criteria outlined in the ATS Official Statement on standardization of spirometry (10) or subsequent revisions of that Statement.

Height should be measured with the subject standing in his or her stockinged feet. If the subject cannot stand or suffers from spinal deformities, height should be considered as equal to the arm span defined as the distance between the tips of the middle fingers when the arms are outstretched (11).

The prediction equations listed in this Statement are those of Crapo and associates (12), which were obtained in a group of nonsmoking, asymptomatic subjects with normal physical examinations and chest roentgenograms.

Studies have documented racial or ethnic differences in the predicted values of FEV_1 and FVC (13, 14). It is recommended that the predicted values be corrected according to formulas given in published works before calculation of the percent of predicted, and that, in any case, a statement be made as to whether or not a correction factor was applied.

Forced expiratory volume in first second (FEV_1). This measurement should be made on the spirogram with the largest FEV_1 value recorded either pre- or post-bronchodilator. The regression equations recommended are shown in table 1.

Forced vital capacity (FVC). The FVC is measured from the tracing with the largest FVC value pre- or post-bronchodilator *even* if that tracing is not the one used for the measurement of FEV_1. The regression equations recommended are shown in table 2.

FEV_1/FVC ratio expressed as a percentage. Using the previously selected values for FEV_1 and FVC, compute the ratio. The regression equations recommended are shown in table 3.

Single Breath Diffusing Capacity

The test for single breath diffusing capacity should be performed by the method of Ogilvie and coworkers (15) or by a comparable method (16). The regression equations of Crapo and Morris (17) are recommended. These values have been normalized to standard hemoglobin concentrations for males (14.6 gm/100 ml) and females (12.8 g/100 ml). (The prediction equation for females is slightly different than that published in the original report (17) because this equation is normalized to a hemoglobin concentration of 12.8 gm/100 ml, rather than 14.6 gm/100 ml). Males: D_{LCOsb} = 0.410 H − 0.210 A − 26.31; females: D_{LCOsb} = 0.267 H − 0.148 A − 10.34; where H = height (cm) and A = age (yr).

Measurements of the single breath diffusing capacity are affected by many factors. A decrease in hemoglobin concentration of 2.5 to 3.0 g% will reduce the value of the single breath diffusing capacity by approximately 10%. Corrections can be made for severe anemia or polycythemia using established procedures (17), but it is recommended that noncorrected values also be recorded. The change in alveolar oxygen tension seen at moderate altitude (5,000 feet above sea level) or with alveolar hypoventilation significantly affects measurements (18). Each laboratory should develop its own quality assurance program for the single breath diffusing capacity.

Tests not Recommended

Maximal Voluntary Ventilation

The maximal voluntary ventilation test is not recommended because it is markedly effort dependent and bears a fixed relationship to the FEV_1 (19).

Miscellaneous Tests of Flow and Volume

The $FEV_{25-75\%}$, closing volume, closing capacity, and volume of isoflow are tests for the detection of early changes in small airways of less than 2 mm internal diameter. They are not recommended for the assessment of impairment because they may be abnormal when overall function as determined by the FEV_1 is normal. On the other hand, one or more of these tests is almost always abnormal when overall function is abnormal, thus adding nothing of clinical significance to the determination of functional impairment.

Rating of Impairment

In the evaluation of respiratory impairment by pulmonary function testing, it is recommended that the first step include *both* forced spirometry measurements and testing for single breath diffusing capacity. With these results, the majority of subjects will be appropriately categorized as to their degree of impairment as follows:

Normal. FVC ⩾ 80% of predicted, *and* FEV_1 ⩾ 80% of predicted, *and* FEV_1/FVC × 100 ⩾ 75%, *and* D_{LCOsb} ⩾ 80% of predicted.

Mildly impaired (usually not correlated with diminished ability to perform most jobs). FVC 60% to 79% of predicted, *or* FEV_1 60% to 79% of predicted, *or* FEV_1/FVC × 100 60% to 74%, *or* D_{LCOsb} 60% to 79% of predicted.

Moderately impaired (progressively lower levels of lung function correlated with diminishing ability to meet the physical demands of many jobs. FVC 51% to 59% of predicted, *or* FEV_1 41% to 59% of predicted, *or* FEV_1/FVC × 100 41% to 59%, *or* D_{LCOsb} 41% to 59% of predicted.

Severely impaired (unable to meet the physical demands of most jobs including travel to work). FVC 50% or less of predicted, *or* FEV_1 40% or less of predicted, *or* FEV_1/FVC × 100 40% or less, *or* D_{LCOsb} 40% or less of predicted.

Periodic reevaluation of functional impairment. Because functional impairment may improve spontaneously, or as a response to therapy, or may progress at varying rates, it is desirable that pulmonary function measurements be repeated. In asthma, or after recent surgery or acute illness, it is mandatory. The intervals for such reevaluation may vary from months to years, depending on the na-

TABLE 2

RECOMMENDED REGRESSION EQUATIONS FOR MEASUREMENT OF FVC

	Units	Equation
Males	L-BTPS	0.0600 H − 0.0214 A − 4.65
Females	L-BTPS	0.0491 H − 0.0216 A − 3.59

For definition of abbreviations, see table 1.

TABLE 3

RECOMMENDED REGRESSION EQUATIONS FOR MEASUREMENT OF FEV_1/FVC RATIO

	Units	Equation
Males	%	−0.1300 H − 0.152 A + 110.49
Females	%	−0.2020 H − 0.252 A + 126.58

For definition of abbreviations, see table 1.

ture of the underlying disease process or intercurrent illness.

Modifying Conditions

Cor Pulmonale

Regardless of the pulmonary function rating of impairment, the presence of cor pulmonale indicates severe impairment.

Arterial Hypoxemia

Arterial blood gas studies should be reserved for selected patients and then performed under rigidly controlled laboratory conditions. The interpretation of the values for arterial oxygen tension should consider the altitude at which the blood specimen is obtained. Arterial blood gas abnormalities must be documented on at least two occasions with an interval between observations of at least 4 wk in clinically stable subjects. Arterial hypoxemia at rest or during exercise is not by itself considered evidence of severe impairment; it must be accompanied by evidence of cor pulmonale. Most subjects who develop exercise induced hypoxemia on the basis of respiratory disease already have impairment on the basis of either spirometric or single breath diffusing capacity measurements, or both (20).

Exercise Induced Bronchospasm

The development of exercise induced bronchospasm does not usually cause a significant respiratory impairment. In most subjects, exercise induced bronchospasm can be prevented with appropriate therapy. In the rare individual, exercise comparable to their usual work activity provokes a reaction that cannot be prevented by therapy. In such a case, the degree of impairment should be assessed using postexercise values and the spirometric criteria as listed in the rating of impairment (see *Rating of Impairment*).

Asthma

An asthmatic is considered severely impaired if carefully documented attacks of bronchospasm, requiring emergency treatment in a hospital or emergency room setting, occur approximately 6 times per year, and prolonged expiration with wheezing or rhonchi is present between attacks, despite optimal therapy, as judged by a physician experienced in the treatment of asthma.

Upper Airway Obstruction

Obstruction of the central airways can cause respiratory impairment. In such subjects, the work of breathing is increased and can influence exercise tolerance. If carbon dioxide retention is present the impairment is severe. If hypercarbia is not present the impairment is partial. Several causes are amenable to operation.

Respiratory Function in Relation to Specific Job Factors

Subjects with respiratory impairment due to pulmonary disease might be able to meet the physical demands of a job, yet might reasonably be considered unfit for a specific job on the basis of two general considerations. First, the job might entail substantial risk of exposures that could cause respiratory injury, in which case the determination of unfitness would be based on the need to avoid further injury to already functionally impaired lungs. Secondly, the job might require the wearing of protective devices (e.g., masks) and evidence that these could not be tolerated or safely used is, in effect, evidence of unfitness for the job. Formulation of a proscription for these various circumstances requires that the physician have knowledge of the risks and requirements of the specific job.

Role of Exercise Testing in the Determination of Impairment due to Respiratory Disorders

Because there is a well documented relationship between FEV_1 and $DL_{CO}sb$ and oxygen consumption and work capacity, it can confidently be predicted that the majority of patients being evaluated for respiratory impairment will not require exercise testing (21–24). Subjects with no or mild impairment (see *Rating of Impairment*) would be able to perform all but the most unusually physically demanding of jobs. Patients with severe impairment usually are unable to perform almost all jobs, if for no other reason than that they are frequently unable to travel back and forth to their place of work.

A person whose job requires sustained moderate exertion or frequent heavy exertion and who complains of shortness of breath while working should be considered a potential candidate for exercise testing. It is not necessary to do exercise testing in all who so complain; the physician should order such testing only when there are grounds for believing that the routine tests may have underestimated the impairment. The exercise testing in such cases is to determine first, whether or not the person is significantly impaired, and secondly, whether the cause of the impairment is due to a respiratory disorder or some other cause. Because of the latter need, the testing must at a minimum include measurement of ventilation ($\dot{V}E$), tidal volume ($\dot{V}T$), and frequency of breathing. Most testing should be done in laboratories that can also measure composition of expired gas and arterial oxygen saturation.

Interpretation of Results

Introduction. In healthy subjects, maximal exercise is limited by heart rate and cardiac output, and not by ventilation or lung function. With maximal exercise, minute ventilation approaches only about 70% of the maximal voluntary ventilation (MVV).

A worker involved in manual labor who is more or less free to set the work pace can work comfortably at approximately 40% of his maximal aerobic power ($\dot{V}O_2max$). During shorter periods of time an individual can work without fatigue at about 50% of his $\dot{V}O_2max$.

It has been estimated that office work requires a $\dot{V}O_2$ of 5 to 7 ml/kg/min, moderate labor requires about 15 ml/kg/min, and strenuous, heavy labor, (e.g., lifting 100 lb, or stevedore work) requires $\dot{V}O_2$ of 20 to 30 ml/kg/min. Athletic activities such as golf require a $\dot{V}O_2$ of 7 to 10 ml/kg/min, tennis a $\dot{V}O_2$ of 12 to 15 ml/kg/min, and marathon running or handball requires a $\dot{V}O_2$ of 25 to 30 ml/kg/min.

Estimation of impairment based on oxygen use. Based on the two concepts discussed above: (*1*) that a worker can perform a job comfortably at 40% of his $\dot{V}O_2max$, and (*2*) that $\dot{V}O_2$ values can be assigned to specific jobs, the following rating of impairment is recommended:

1. If $\dot{V}O_2max$ is greater than or equal to *25 ml/kg/min* (7.1 METS), the subject will be capable of continuous heavy exertion throughout an 8-h shift and of all but the most physically demanding of jobs. In rare cases, some subjects with respiratory disorders have an unusually high work of breathing, and the majority of the oxygen uptake during exercise is consumed by the muscles of respiration. Usually, 100 kpm/min of work is performed for every MET of oxygen consumption. If the work-to-oxygen consumption ratio is substantially less than this value, $\dot{V}O_2$ max will not reflect actual work capacity.
2. If the subject's oxygen consumption is between *15 and 25 ml/kg/min*, and 40% of his observed $\dot{V}O_2max$ is greater than or equal to the average metabolic work requirement of his job, then the subject should be able to perform that job comfortably (25). An exception would be a job which demands frequent and extended periods (>5 min) of exertion requiring substantially greater than 40% of the $\dot{V}O_2max$.
3. If $\dot{V}O_2max$ is less than or equal to *15 ml/kg/min* (4.3 METS), the subjects will be unble to perform most jobs because they would be uncomfortable in traveling back and forth to their place of employment.

Criteria for ascertainment of respiratory limitation of measured exercise capacity (26, 27): (*1*) exercise not terminated for other reasons; and (*2*) low breathing reserve (BR) at termination of exercise (BR = MVV calc − $\dot{V}Emax$); and (*3*) absence of erratic overventilation of submaximal levels, with failure to achieve anaerobic threshold (i.e., absence of evidence of psychogenic dyspnea).

Impairment not Directly Related to Reduced Lung Function

Sensitization from Workplace Environment

Asthma

Asthmatics may be considered severely impaired for particular jobs for one of two general reasons. First, acute attacks of asthma may result from sensitization to agents found only in the workplace (occupational asthma). Secondly, the patient with ordinary asthma has a propensity for sensitization and cannot prudently work in high levels of sensitizing pollutants or around any highly potent sensitizer. Acute attacks of asthma may also result from exposure to nonspecific airborne irritants in the workplace such as dusts, fumes, gases, or smoke. Because many subjects who complain of industrial asthma do not have objective evidence of work environment induced bronchospasm, it may be necessary to document significant decline in FEV_1 by testing before and after workplace exposure.

HYPERSENSITIVITY PNEUMONIA (EXTRINSIC ALLERGIC ALVEOLITIS)

In hypersensitivity pneumonia, as in asthma, specific proscriptions are directed against the risk of further acute attacks either from exposures to the causative agent or to other agents with similar sensitizing properties.

Pneumoconiosis

The diagnosis of a pneumoconiosis generally warrants prohibition of further occupational exposure to the causative agent. Such a prohibition is not obviated by a showing that current exposure is within legally permissible limits, because such limits are not presumed to provide adequate protection for persons who already manifest the disease. However, such prohibitions are relative rather than absolute. An older worker with a mild pneumoconiosis may be at low risk from working in currently permissible exposure levels until he reaches retirement age; both the worker and his employer must have factual information to make informed decisions about such risks.

Sleep Disorders

Sleep related breathing disorders (sleep apnea) are caused by periodic cessation of respiration associated with decreases in arterial oxyhemoglobin saturation and frequent arousals from sleep (28). In some patients, this disturbed sleep pattern and chronic nocturnal hypoxemia can cause daytime hypersomnolence with disturbances in cognitive function and pulmonary hypertension (29, 30).

Only some individuals with sleep apnea develop a functional impairment that affects work activity. These disorders can cause physiologic changes which result in cor pulmonale, a cause of *severe* impairment. Severe sleep apnea can also result in deterioration of daytime cognitive performance which may interfere with work activities that require constant vigilance. Therefore, jobs such as long distance truck driving, operation of potentially dangerous machinery, and the like, should be proscribed for such individuals.

Cough Syncope

Somewhat analogous to sleep disorders, cough syncope is a cause of impairment because of the potential of loss of consciousness. Thus, jobs which require vigilance should be proscribed.

Pulmonary Diseases in Relation to Specific Jobs

BULLOUS DISEASE OF THE LUNG

Subjects with bullae in the lung are at increased risk of developing spontaneous pneumothorax from the barotrauma incident to deep sea diving and aviation jobs and should be considered unfit for such jobs.

RECURRENT PNEUMOTHORAX AND RECURRENT PULMONARY HEMORRHAGE

Because of the unpredictability of their occurrence, subjects with these conditions should be deemed unfit for any job that is remote from adequate emergency medical facilities.

Miscellaneous

There are respiratory disorders which cause impairment whose basis is their effect on overall body function rather than their respiratory effects. Lung neoplastic malignancies, pulmonary vasculitidies, and severe chronic and progressive pulmonary infections produce impairment as a result of weight loss, muscle weakness, and general debility. The degree of impairment in such situations will depend on the ability of the subject to carry out self care and work related activities with comfort. Degrees of impairment cannot be generally categorized in any meaningful way to cover all such circumstances and are best left to the judgment of attending and consulting physicians.

Special Considerations when Interpreting and Reporting Findings

Applicant Not Properly Diagnosed or Treated

The name or diagnosis given to the symptoms or syndrome that the medical profession accepts as evidence of ill health has importance for purposes of impairment/disability evaluation. The diagnosis provides a means to decide upon the type of evidence necessary to describe impairment and the form of examination and laboratory procedures necessary for diagnosis. If an earlier diagnosis is incorrect, the examiner should submit the correct diagnosis.

Applicant Refuses or Has Not Received Commonly Accepted Regimen of Therapy

By definition, regardless of the reason(s) given, decisions concerning impairment should not be made until after appropriate therapy has been received and only when there appears to be no reasonable prospect of further improvement. If the applicant is not being treated or has refused therapy generally considered likely to improve his condition, this should be recorded. Treatment for primary or metastatic malignant solid tumors of lung or pleura are excluded from this section because of low likelihood of sustained improvement or cure.

Applicant Has Coexisting Diseases

When two disease processes coexist, it is important to present a separate evaluation for each diagnostic entity and indicate the major impairing condition. The examination should be sufficiently detailed in order that this distinction can be made. Although each disease by itself may not be disabling, the sum of the disorders may be.

Applicant's Refusal or Inability to Cooperate During Examination

If there is an unreasonable refusal or inability on the part of the claimant to cooperate in the performance of the requested studies, this should be recorded.

Applicant Deconditioned

A state of poor conditioning should be noted when the level of impairment is substantially attributable to a deconditioned state.

Applicant Beyond Retirement Age

Age, per se, is irrelevant in determining respiratory impairment but is important in the determination of disability.

This statement was prepared by the Ad Hoc Committee on Impairment/Disability Evaluation. Members of the Committee were:

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10

American Thoracic Society

MEDICAL SECTION OF THE AMERICAN LUNG ASSOCIATION

EVALUATION OF IMPAIRMENT/DISABILITY SECONDARY TO RESPIRATORY DISEASE

THIS OFFICIAL ATS STATEMENT WAS ADOPTED BY THE ATS BOARD OF DIRECTORS, JUNE 1982

There are several classification schemes used for defining the degree of respiratory impairment (1–7). Some of these schemes are based on actual values of pulmonary function tests (3,4), while others use predicted values (6–8). One scheme is based on severe dyspnea (5). The Component Committee for Disability Criteria of the American Lung Association has reviewed these programs, as well as the best information available, in their efforts to develop impairment/disability criteria in respiratory disease that would standardize one's assessment of respiratory impairment. These recommendations are intended to apply equally to occupational as well as nonoccupational respiratory disease of any type.

A distinction has been made between the terms impairment and disability and the following definitions are presented:

Impairment: This is purely a medical condition. It reflects a functional abnormality that persists after appropriate therapy and with no reasonable prospect of improvement. It may or may not be stable at the time the evaluation is made. If severe, it frequently precludes gainful employment. It is always a basic consideration in the evaluation of disability.

Disability: A term that indicates the total effect of impairment upon a patient's life. It is affected by such diverse factors as age, gender, education, economic and social environment, and energy requirements of the occupation.

Two people with an identical impairment may be differently affected in their life situations.

The Committee believes that rating of health impairment falls within the province of a physician's expertise to quantitate. Determination of disability is an administrative decision that requires consideration of many nonmedical as well as medical variables.

I. Identifying Pulmonary Impairment

History, physical examination, chest radiographs, and pulmonary function tests are needed to establish a diagnosis and/or provide a frame of reference.

1. Medical History

Although comprehensive, the history taking should particularly address the specific problems of pulmonary impairment. For those who have an interest in developing epidemiologic data, the questionnaire of the American Thoracic Society's Epidemiology Standardization Project may be suitable (9). For those who do not prefer to use such a questionnaire, the history should include the following:

(1) Demographic and Clinical Information

(A) Identification

Basic information includes name, address, social security number, telephone number, date and places of birth and residence, age, and gender. The patient's race, marital status, highest grade completed in school, regularity and extent of exercise, may be helpful in selected situations.

(B) Dyspnea

One of the manifestations of reduced lung function and impairment is shortness of breath. The degree of dyspnea can be estimated by determining activities that provoke shortness of breath, i.e., distance walked, number of stairs climbed, etc. Dyspnea cannot be used as a sole criterion for evaluating impairment because the causes of dyspnea are multiple and complex. Furthermore, individual responses to a given degree of dyspnea vary and are influenced by factors unrelated to the extent of lung disease such as difficulty of verbal communication, preoccupation with health, and socioeconomic and educational backgrounds. Dyspnea should therefore be considered in combination with other clinical and physiologic factors (1, 2, 10–13).

(C) Cough, Sputum Production

Although cough occurs frequently in patients with chronic obstructive pulmonary diseases (COPD), only some will meet the criteria of chronic bronchitis, i.e., cough productive of daily sputum for at least three months out of the year for two consecutive years without other apparent cause. Thus, a detailed description of sputum as to volume, color, odor, consistency, and when expectorated, becomes important. Simple streaking of blood in the sputum may be observed in chronic bronchitis.

(D) Wheezing

The hallmark of reversible airway obstruction is the wheeze. Wheezing is so common in asthma that it is frequently forgotten that "all that wheezes is not asthma." Foreign bodies or tumors in airways can cause wheezing. Such wheezing is usually confined to one area of the chest. Wheezing may occur in patients with congestive heart failure. Usually these findings are of brief duration and associated with obvious signs of cardiovascular decompensation. An ominous sign in status asthmaticus is the absence of wheezing. Wheezing is presumably absent because the flow rates are low or the airways are filled with mucus, thus reducing the ventilation to large areas of the lungs. No discussion of wheezing is complete without a description as to frequency; occurrence during day, year; identification of causative factors; whether it limits one's capacity to function, etc.

(E) Environmental Exposure and Chronologic Occupational Data

Public awareness of the dangers associated with certain occupations has increased in recent years. However, enough workers are not familiar with occupational hazards to justify traditional screening questions related to mining, rock drilling, sand blasting, etc. Job titles such as "plasterer," "fireman," or "engineer" may be of little value because official titles tend to remain the same while job activities and hazardous exposures may change dramatically as a result of the development of new technology.

A detailed history of the employee's employment background should be presented in chronologic order. Vacation and part-time school employment, etc. should be included. In some cases, the spouse's job and exposure may be helpful. Finally the presence of pets, the use of forced air humidifiers, and the nature of hobbies should be determined. The employee should be questioned about specific hazardous

Reprints may be requested from your state or local Lung Association.

dust or fume exposure. If such an exposure occurred, the following indexes are helpful: (*1*) year first exposed to hazardous agent, (*2*) total years exposed, (*3*) estimation of the hazard level, and (*4*) years since last exposed.

(F) Use of Tobacco

Subjects should be classified as nonsmokers (never smoked), ex-smokers (stopped for at least one year), and present smokers. The smoking history should list type(s) of tobacco smoked (cigarette, pipe, or cigar), with an emphasis on cigarette smoking. The history should include such information as to age when the subject first started to smoke, the brands used, if and when the use of cigarettes was discontinued, and an estimate of pack-years smoked. Maximal smoking levels should be determined.

2. Physical Examination

Physical examination *should* contain specific observations that will enable the reviewer to obtain an understanding of the claimant's respiratory problem:

(1) General Description

Notation should be made as to the patient's position (standing, sitting, or supine) at the time blood pressure, heart, and respiratory rates are recorded. Height and weight should be noted, preferably in the metric system. Do the following occur during inspiration: *en bloc* movement of the chest, use of sternocleidomastoid and accessory muscles, paradoxical movement of the intercostal spaces posterolaterally and an attempt to elevate the chest cage by fixing the shoulders and leaning forward? Record the degree of thoracic muscle wasting, position, and extent of diaphragmatic motion as well as paradoxical movement between rib cage and the abdomen.

(2) Description of the Patient's Breathing

Does the patient exhale through pursed lips? Depth of breathing, tachypnea, hyperpnea, labored breathing at rest, as well as the inability to complete sentences because of dyspnea should be recorded. By listening over the trachea with a stethoscope, the forced expiratory flow following a maximal inspiration can be timed. Normally this takes less than four seconds, whereas it may take several times this in patients with airflow limitation.

(3) Cyanosis and Clubbing

In the presence of a normal hemoglobin concentration, cyanosis (central) involving the buccal mucosa and lips may not be seen until the arterial blood oxygen saturation is less than 75%. Clubbing, almost invariably absent in COPD but which occurs when lung abscess, empyema, bronchiectasis or asbestosis coexist, should consist of four components: softness of the nail bed, curvature of the nail, increase in soft tissue of the fingertips, and increased hyponychial angle of the right index finger (14).

(4) Adventitious Lung Sounds

The character of lung sounds should be noted during quiet and deep breathing. The relative duration of expiration and inspiration as well as the intensity of breath sounds can provide valuable information concerning obstruction to air flow. The latter has correlated well with pulmonary function measurements (15). Wheezing or rhonchi and crackles (rales) should be described as to intensity, location, and relationship within the respiratory cycle, i.e., inspiration, expiration, or both. Crackles may be present in two-thirds of patients with chronic interstitial disease such as asbestosis and desquamative interstitial pneumonia. These crackles usually occur during late inspiration and are described as fine end-inspiratory crackles (16). Early inspiratory crackles may be heard in diseases of air flow obstruction and particularly in bronchiolitis obliterans (17).

(5) Cor Pulmonale

The term cor pulmonale means pulmonary heart disease and is associated with chronic diffuse interstitial disease, etc. If right heart failure accompanies cor pulmonale, neck vein distension occurs above the upper level of the manubrium sterni when the patient is lying supine. These veins fill from below, and their volume does not decrease when the thorax is elevated to a 45 degree angle from the horizontal. Dependent edema, increased hepatic size in the right midclavicular line, or both may confirm the existence of heart disease if these findings are not secondary to other causes. Not uncommonly along the left sternal border or over the epigastrium there is a right ventricular early diastolic gallop rhythm that tends to be increased on inspiration (18).

3. Chest Roentgenograms

Minimal radiographic examination should consist of posterior-anterior (PA) and lateral views taken on deep inspiration. Chest radiographic findings often correlate poorly with physiologic findings in diseases of airflow limitation such as asthma and emphysema. No correlation between work status and roentgenographic findings has been noted. However, as part of the overall evaluation for impairment/disability, the chest radiograph should be described in terms of hyperinflation, loss of vascular markings, presence of bullae, flattened diaphragms, increase in retrosternal air space, sternophrenic angle, and PA diameter. Cardiac abnormalities or evidence of cor pulmonale should be noted. Finally, almost 10% of patients with histologically-confirmed diffuse infiltrative disease had normal film findings before biopsy (19).

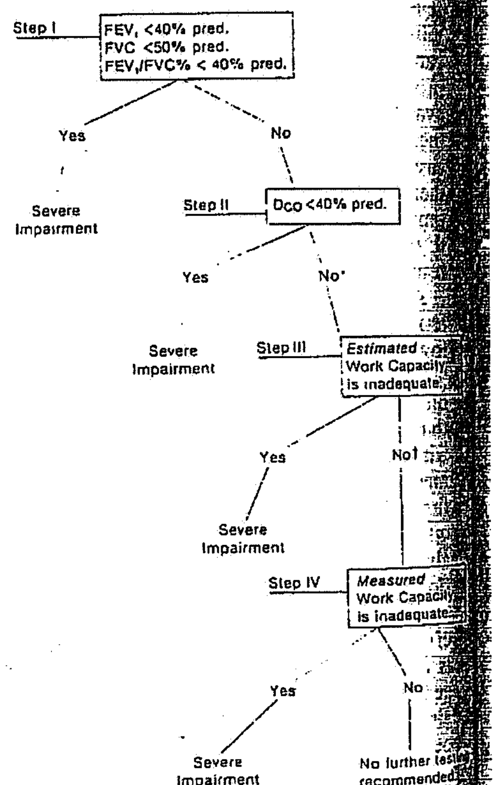
In diseases with rounded opacities, such as coal worker's pneumoconiosis, correlation between physiologic and roentgenographic abnormalities is poor. The only exception is when there is radiographic evidence of progressive massive fibrosis (PMF). As the PMF intensifies there is sometimes a significant reduction in the ventilatory capacity.

If the disease is a mixed reticular-nodular pattern such as sarcoidosis, the correlation is frequently quite poor. However, the extent of diffuse linear opacities seen in interstitial pneumonias or asbestosis, correlate with physiologic abnormalities (20). Although previously suggested (21), the Committee believes that the recently revised international code (ILO 1980) (22) for pneumoconiosis classification should be used in describing all types of diffuse interstitial lung disease.

II. Rating of Respiratory Impairment

1. Test Schema

The Committee recommends the following test schema for determining whether an individual is severely impaired by respiratory disease. (See text for further explanation.)



* If FEV_1, FVC, FEV_1/FVC%, and Dco are above the lower "cut-off" limits—stop.
† Not sure, see text when next step in Test Schema should be requested.

2. Selection of Tests

(1) Forced Spirometry Measurements (Step I)

Three measurements of pulmonary function are included in this step, i.e., FVC, FEV_1, and FEV_1/FVC%. If the results recorded in *any* of the three measurements are below the lower "cut-off" limits, the individual is declared severely impaired, and *no* further pulmonary function testing will be requested.

The subjects should be evaluated after they have received optimum therapy and are at their optimal health condition. If wheezing or other evidence of bronchospasm is present at the time of the examination, the ventilatory studies should be repeated after the administration of a bronchodilator. If isoproterenol is used, one should wait ten minutes after administering two inhalations or a dose of 250 μg. If either metaproterenol or isoetharine is used, one should wait 15 to 20 minutes before repeating the spirometric studies.

The spirometric measurements should be performed as described in the Epidemiology Standardization Project (9). The equipment, methods of calibration, and technique used should meet the criteria outlined in the ATS Official Statement, "Standardization of Spirometry" (23).

Height should be measured with the subject standing in his/her stocking feet. If subject cannot stand, or suffers from spinal deformities, height should be considered as equal to the arm span (maximal distance between the tips of the middle fingers when the arms are stretched out against the wall) (24).

The Committee acknowledges that studies have documented that the FVC and FEV_1 of black males are somewhat lower than those for white males of the same age and height (25, 26). However, a separate prediction equation is not recommended because such equations are not available for other ethnic groups.

The prediction equations listed in this report are those of Crapo et al. (27), which were obtained in a group of nonsmoking, asymptomatic subjects with normal physical examinations and chest roentgenograms.

When the Committee selected the FEV_1, FVC, and FEV_1/FVC% as the tests for classifying severe impairment, it had to decide between using actual or predicted values. This posed certain philosophical as well as scientific questions (28, 29). *Because the physician is concerned primarily with the definition of impairment and not the direct determination of disablement, the Committee recommends the use of percent predicted value where ratings of impairment compares the individual's organ function with a comparable group of healthy individuals.*

(A) Forced Expiratory Volume in First Second (FEV_1)

The measurement should be made on the best spirogram recorded either pre- or post-broncodilator. *If a subject has a FEV_1 of 40% of predicted or less, this individual is eligible for a severe impairment rating (7).* The lower limit of normal of the FEV_1 is equal to the value obtained when the 95% confidence interval is subtracted from the predicted value. The regression equations of Crapo et al. (27) are acceptable for predicted values:

Test	Units	Equation	95% Confidence Interval
Males			
FEV_1	L-BTPS	0.0414H-0.0244A-2.190	0.842
Females			
FEV_1	L-BTPS	0.0342H-0.0255A-1.578	0.561

L-BTPS = liters at BTPS; H = height (cm); A = age (years).

(B) Forced Vital Capacity (FVC)

The FVC is measured along with the FEV_1. *If a subject has a FVC of 50% of predicted or less, this individual is eligible for a severe impairment rating* (7). The lower limit of normal of the FVC is equal to the value obtained when the 95% confidence interval is subtracted from the predicted value. The regression equations of Crapo and associates (27) are acceptable for predicted values:

Test	Units	Equation	95% Confidence Interval
Males			
FVC	L-BTPS	0.0600H-0.0214A-4.650	1.115
Females			
FVC	L-BTPS	0.0491H-0.0216A-3.590	0.676

L-BTPS = liters at BTPS; H = height (cm); A = age (years).

(C) FEV_1/FVC Ratio Expressed as a Percentage

If a subject has a FEV_1/FVC% of 40% of predicted or less, this individual is eligible for a severe impairment rating. Kanner and associates (30) have found that these individuals have a statistically significant shortened life span. The lower limit of normal is equal to the value obtained when the 95% confidence interval is subtracted from the predicted value. The regression equations of Crapo et al. (27) are acceptable for predicted values:

Test	Units	Equation	95% Confidence Interval
Males			
FEV_1/FVC	%	− 0.1300H-0.152A + 110.49	8.28
Females			
FEV_1/FVC	%	− 0.2020H-0.252A + 126.58	9.06

H = height (cm), A = age (years).

(2) Diffusing Capacity (Step II)

The D_{CO} should be performed when respiratory complaints continue unabated in spite of forced spirometric measurement results above the cut-off limits.

The methodology for performing the single breath diffusing is basically that described in the 1978 American Thoracic Society Epidemiology Standardization Project (pp. 62–72) (9). Crapo and Morris (31) have derived prediction equations based on measurements of D_{CO} in a large group of nonsmoking, asymptomatic subjects with normal physical examinations and chest roentgenograms. These values have been normalized to standard hemoglobin concentrations for males (14.6 gm/100 ml) and females (12.8 gm/100 ml)[1]:

	95% Confidence Interval
Males	
D_{CO} = 0.410H − 0.210A − 26.31	8.2
Females	
D_{CO} = 0.267H − 0.148A − 10.34	5.7

H = height (cm), and A = age (years).

If a subject has a D_{CO} of 40% of predicted or less, this individual has severe impairment (7). The lower limit of normal is equal to the value obtained when the 95% confidence interval is subtracted from the predicted value.

Measurements of the diffusing capacity are affected by many factors. A decrease in hemoglobin concentration of 2.5–3.0 gm% will reduce the value of the diffusing capacity by approximately 10%. Corrections can be made for severe anemia or polycythemia using established procedures (31). The change in alveolar oxygen tension seen at moderate altitude (5,000 feet above sea level) or with alveolar hypoventilation theoretically may affect measurements by as much as 5%. However, these are secondary effects that usually are of little significance and are smaller than the variability of the test itself. Ideally, each laboratory should develop its own prediction equations based on studies obtained in a reasonably large number of subjects. This is particularly important if measurements are made under different conditions or using different procedures than those recommended. Alternatively, appropriate prediction equations from the literature may be used if they were obtained under similar experimental circumstances.

(3) Estimated Work Capacity (Step III)

Maximal oxygen uptake achieved during graded increments of exercise provides an objective measure of an individual's capacity to work. Oxygen uptake can be measured directly or estimated from power output generated during treadmill or ergometer exercise.

Work capacity studies are *not* recommended for individuals whose Steps I and II pulmonary function study results are either within the 95% confidence interval or less than 40% predicted. The Committee, however, recommends the use of work capacity studies under the following circumstances:

[1] The prediction equation for females is slightly different than that published in the original report (31), because this equation is normalized to a hemoglobin concentration of 12.8 gm/100 ml rather than 14.6 gm/100 ml.

When the results of the Step I and II pulmonary function tests are above the severe impairment cut-off point or below the 95% confidence interval and the claimant states he/she is physically unable to meet the demands of a specific job because of breathlessness.

When the claimant has not performed maximally or correctly in the Step I and II studies.

Exercise testing should not be performed on individuals who have medical contraindications in the opinion of the examining physician.

The criteria for stopping the test include: extreme fatigue, intolerable leg muscle pain, a decrease or lack of increase in systolic blood pressure with increasing workload, an increase in diastolic pressure of more than 20 mmHg above the resting value, severe systolic hypertension (greater than 260 mmHg), a burst of three or more successive premature ventricular contractions, recurring multifocal premature ventricular contractions, major left intraventricular conduction disturbance, symptomatic ST-T segment depression or elevation greater than 2.0 mm, tachyarrhythmia greater than 85% of the age adjusted heart rate maximum, signs of insufficient peripheral circulation or cardiac output, i.e., pallor, cyanosis, clammy skin, nausea, dizziness, or muscle cramps (32, 33).

The Committee reviewed a number of articles (34–39) and decided to follow the exercise testing procedure described by Jones (40) in estimating the work capacity. The $\dot{V}O_2$ is not measured directly but rather can be obtained once the power output (KPM/min) is determined. Through the use of the Wick's graph (40), one can obtain comparable power output results with either the cycle ergometer or the treadmill (Appendix A). Formulas for calculating the energy requirements for various activities such as treadmill walking, jogging/running, bicycle ergometry, etc., are presented in reference 41.

An incremental work test is most commonly used to obtain the maximum power output. On a cycle ergometer the subject starts exercising at 100 KPM/min and the power output is increased by 100 KPM each minute.

Small women and children start at 50 KPM and are increased by 50 KPM each minute (40). Ideally, the treadmill test should be performed at three mph (Wick's protocol [38]), but it may be necessary to start at a slower speed and increase it each minute, i.e., 1.5 mph 0% grade for one minute, 2.5 mph 0% grade for one minute, and 3.0 mph 0% grade for one minute. Finally, leave speed at 3.0 mph and increase grade by 2.5% each minute. The latter will increase work by increments of approximately 100 KPM/min.

Because of a linear relationship between $\dot{V}O_2$, heart rate, and ventilation, a concomitant rise in the latter two should be recorded during exercise (34, 42). If maximal heart rate values are of the order of 210 (0.65 × years), the participant is probably being adequately stressed (40). On average, when the subjects are working up to about 85% of their maximal heart rate, they have reached 75 to 85% of their $\dot{V}O_2$ max (43, 44). A reduction in the ventilatory capacity will also limit exercise ventilatory capacity ($\dot{V}_E$) and exercise will cease at a $\dot{V}O_2$ below the predicted maximum. In 1975, Spiro and associates (34, 45) presented this relationship for determining whether the $\dot{V}O_2$ max is acceptable in the COPD patients by comparing the observed $\dot{V}_E$ with the predicted ventilatory capacity which he calculated as follows:

$$\dot{V}_E = (FEV_1 \times 18.9) + 19.7.$$

For normal subjects or patients with nonobstructive pulmonary defects, Jones (40) finds that the maximum ventilation able to be sustained during four minutes of exercise is:

$$\dot{V} = FEV_1 \times 35.$$

The equipment required for Step III includes a carefully calibrated treadmill or cycle ergometer, an electrocardiograph for recording the heart response to exercise, low resistance valve, and a means of accurately measuring minute ventilation. If hypoxemia is anticipated during exercise, ear oximetry is simple and often helpful. A 5% drop in the Sa_{O_2} is considered meaningful. There should be ready access to emergency equipment and drugs (33, 44, 46).

The Committee has reviewed the findings of Roemmich and associates (47). Coal miners taller than 165.1 cm (5 ft. 5 in.), provided the FEV_1 was over 50% of the predicted figure, were capable of sustaining a level of work requiring a $\dot{V}O_2$ max of 1.75 L/min or 7.0 + METS.[2] This level of work is relatively strenuous and in excess of the usual energy demands made on coal miners. Michael et al. (48) noted that their subjects could walk on a treadmill for eight hours, without undue fatigue, if the energy costs did not exceed 35% of the $\dot{V}O_2$ max. Three observations presented by Astrand were also evaluated (44):

Working at his/her own pace, work output can be sustained for an eight-hour period if one does not exceed 40% of his/her attained $\dot{V}O_2$ max.

For shorter periods of time one can work effectively at about 50% of achieved $\dot{V}O_2$ max.

If one functions under test conditions for at least five minutes at a rate of work demanding a $\dot{V}O_2$ of 2.5 L/min, he/she can most likely work under steady state conditions for hours with a $\dot{V}O_2$ of [illegible] L/min.

The Committee thus considers the claimant to be severely impaired if 30–40% of his/her observed $\dot{V}O_2$ max does not allow the claimant to meet the $\dot{V}O_2$ costs of his/her occupational activities over an eight-hour period (43, 49–51). If a $\dot{V}O_2$ max of 15 ml/(kg · min) cannot be reached, the participant should be considered impaired for practically all types of labor (42).

(4) Measured Work Capacity (Step IV)

Measured work capacity studies should be requested whenever one is not sure that the work capacity was properly recorded in the Step III study. The following could serve as a basis for doubt:

Inappropriate changes observed in either the heart rate and/or $\dot{V}_E$.

Subject unable to complete the test because of nonrespiratory symptoms, i.e., leg muscle fatigue, etc.

Doubt about the predominant factor(s) responsible for the respiratory symptoms.

Step IV exercise protocol can be either that used by Jones (40) or one the performing laboratory regularly uses. If the Jones approach is used, the subject will be studied in the steady state[3] at rest and at one third and two thirds of the maximum power output obtained during the Stage III incremental work test. An arterial blood specimen obtained during exercise may provide additional valuable data concerning pulmonary gas exchange.

Other details concerning the performance of Step IV *per se* can be found in the narrative presented in Step III as well as the following references (52–54).

The definition of severe impairment is the same as presented for Step III.

(5) Arterial Blood Gases

Abnormal arterial blood gas values can be a partial reflection of chronically impaired lung function. For the obstructive lung diseases, the FEV_1 correlates better with an ability to work than the resting Pa_{O_2} level (55). The Committee does not recommend arterial blood gases for initial screening. If hypoxemia is suspected, these studies can be utilized at Step III or IV of the evaluation.

Arterial blood gas studies should be reserved for selected cases and then performed under rigidly controlled laboratory conditions.

An individual is impaired if he/she is in a stable condition, is receiving optimal medical therapy, and meets either of the following criteria:

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[2] METS is an abbreviation for multiples of the resting energy requirement, assumed to be 3.5 ml O_2/(kg · min).

[3] Steady state. Variations of less than ± five beats in the cardiac frequency, of less than ± three mm Hg in end-tidal Pco_2, and of less than ± 0.1% in expired CO_2 and O_2 concentrations indicate an adequate steady state (40).

(1) Resting arterial $Po_2 < 55$ mm Hg while breathing room air

(2) Resting arterial $Po_2 < 60$ mm Hg while breathing room air together with evidence of one or more of the secondary conditions related to arterial hypoxemia (56) including:

- Pulmonary hypertension as determined by cardiac catheterization.
- Cor pulmonale as exhibited by electrocardiographic and chest radiographic changes.
- Increasing severity of hypoxemia as noted by blood samples from an indwelling arterial cannula or by the ear oximeter while exercising on a treadmill for no more than six minutes at two mph, zero% grade.
- Erythrocytosis confirmed by complete blood count, and if necessary, the use of radioactive nuclides to measure red blood cell mass and plasma volume.

Patients with chronic obstructive pulmonary disease meeting these criteria have a significantly improved survival when treated with continuous oxygen therapy (57). The values for arterial Po_2 in these guidelines should be appropriately adjusted to reflect the altitude at which the blood specimen is obtained. Hypoxemia must be documented on two occasions with an interval between observations of at least four weeks because many patients will improve significantly during this time when receiving optimal medical care (58).

(6) Other Tests (Not Recommended)

(A.) Maximum Voluntary Ventilation

The maximum voluntary ventilation (MVV) first presented in Germany more than 40 years ago was useful because the FEV_1 had not been described (59). It is not as useful as the FEV_1 for the following reasons:

- The test has a much larger learning effect.
- It is much more fatiguing.
- Because of the more rapidly changing flow rates, the instrument requirements are more rigid.
- In interstitial disease, the MVV may be normal even when there is a severe impairment of gas exchange.

The 1978 ATS Epidemiology Standardization Project lists the MVV as an optional pulmonary function test (9).

(B.) Miscellaneous Tests of Flow and Volume

The $FEF_{25-75\%}$, closing volume, closing capacity, and volume of isoflow are tests that appear to detect changes in small airways of less than two millimeters internal diameter and are not recommended for the assessment of impairment.

III. Special Considerations when Interpreting and Reporting Findings

1. Applicant Severely Impaired by Asthma

An asthmatic is considered severely impaired if carefully documented severe attacks of bronchospasm requiring emergency treatment by a physician occur at least once every two months or on an average of at least six times per year despite therapy judged as optimum by a specialist in respiratory disease. The claimants should have prolonged expiration with wheezing or rhonchi between attacks to meet criteria established by the Social Security Administration (32).

2. Applicant Not Properly Diagnosed and/or Treated

The name or diagnosis given to the symptoms or syndrome that the medical profession accepts as evidence of ill health has importance for purposes of impairment/disability evaluation. The diagnosis provides a means to decide upon the type of evidence necessary to describe impairment and the form of examination and laboratory procedures necessary for diagnosis. Clearly, if an earlier diagnosis is incorrect, the examiner should submit the correct diagnosis.

3. Applicant Refuses or Has Not Received Commonly Accepted Regimen of Therapy

By definition, regardless of the reason(s) given, decisions concerning severe impairment should not be made until after appropriate therapy and only when there appears to be a reasonable prospect of no further improvement. If the participant is not being treated or has refused therapy generally considered likely to improve the claimant's condition, this should be recorded.

4. Applicant Has Coexisting Diseases

When two disease processes coexist, it is important to present a separate evaluation for each diagnostic entity and indicate the major impairing condition. The examination should be sufficiently detailed in order that this distinction can be made. Although each disease by itself may not be disabling, the sum of the disorders may be.

5. Applicant's Refusal or Inability to Cooperate During Examination

If there is an unreasonable refusal or inability on the part of the claimant to cooperate in the performance of the requested studies, this should be recorded.

6. Applicant Deconditioned

A state of poor conditioning should be described when the level of impairment is primarily attributable to a deconditioned state resulting from illness, recent hospitalization, physical inactivity, obesity, malnutrition, etc.; this fact(s) should be recorded and retesting after appropriate remedial action should be recommended.

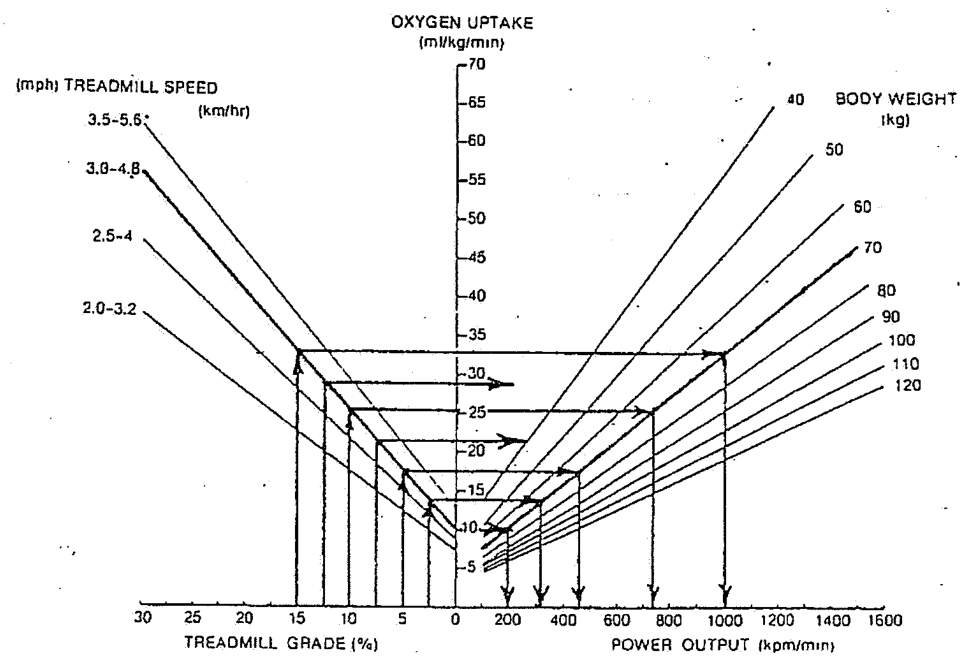
7. Applicant Beyond Retirement Age

Retirement age is irrelevant in determining cardiopulmonary impairment, but is important in a disability evaluation. Established procedures prevail for anyone referred for an evaluation.

8. Death Cases

Whenever possible, obtain all medical evidence, including the death certificate, that may help in the determination of impair-

Appendix



Equivalent Power Output Graph

ment and/or disability. The death certificate by itself is never sufficient.

9. Applicant Has Disability Without Impairment

Just as impairment can exist without disability, the reverse is true. Tuberculosis, bronchiectasis, sleep apnea (alveolar hypoventilation syndrome) are examples whereby disability can exist without measurable lung function impairment.

Appendix A

Using the Wicks graph (40), the treadmill speed and elevation are converted into an equivalent power output obtained with a cycle ergometer as follows: A 70-kg subject is exercised at three mph, using progressive increments in elevation of 2.5% each minute (38). A vertical line is drawn from the Treadmill Grade (%) to the speed isopleth. A horizontal line is next drawn to the isopleth for the subject's weight. Then a vertical line is dropped to the Power Output line. This is repeated for each increment of elevation reached.

The graph may also be used to predict the $\dot{V}O_2$ from the data obtained during both the treadmill and cycle ergometer tests. Prediction equations are available to provide the same information (40, 41).

Prediction of Maximal O_2 Intake ($\dot{V}O_2$ max) (40):

Males

$\dot{V}O_2$ max = 4.2 − 0.032 age L/min (SD ± 0.4)
$\dot{V}O_2$ max = 60 − 0.55 age ml/kg·min (SD ± 7.5)

Females

$\dot{V}O_2$ max = 2.6 − 0.014 age L/min (SD ± 0.4)
$\dot{V}O_2$ max = 48 − 0.37 age ml/kg·min (SD ± 7.0)

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(Rev. 80)

OCCUPATIONAL SAFETY
AND HEALTH SERIES

GUIDELINES FOR THE USE OF ILO INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF PNEUMOCONIOSES

REVISED EDITION 1980

INTERNATIONAL LABOUR OFFICE GENEVA

The International Programme for the Improvement of Working Conditions and Environment (PIACT) was launched by the International Labour Organisation in 1976 at the request of the International Labour Conference and after extensive consultations with member States.

PIACT is designed to promote or support action by member States to set and attain definite objectives aiming at "making work more human". The Programme is thus concerned with improving the quality of working life in all its aspects: for example, the prevention of occupational accidents and diseases, a wider application of the principles of ergonomics, the arrangement of working time, the improvement of the content and organisation of work and of conditions of work in general, a greater concern for the human element in the transfer of technology. To achieve these aims, PIACT makes use of and co-ordinates the traditional means of ILO action, including:

- the preparation and revision of international labour standards;
- operational activities, including the dispatch of multidisciplinary teams to assist member States on request;
- tripartite meetings between representatives of governments, employers and workers, including industrial committees to study the problems facing major industries, regional meetings and meetings of experts;
- action-oriented studies and research; and
- clearing-house activities, especially through the International Occupational Safety and Health Information Centre (CIS) and the Clearing-house for the Dissemination of Information on Conditions of Work.

The Clearing-house for the Dissemination of Information on Conditions of Work aims to set up a network of institutions which will forward information about their research projects, meetings, publications and training activities on a regular basis. Its computerised data base will provide quick access to this information, which will be disseminated to institutions in various forms, including replies to ad hoc requests.

This publication is the outcome of a PIACT project.

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Guidelines for the use of ILO International Classification of Radiographs of Pneumoconioses

Revised edition 1980

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GUIDELINES FOR THE USE OF ILO INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF PNEUMOCONIOSES

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FOREWORD

During the past 50 years the International Labour Office has promoted discussion and published a series of guidelines on ways of classifying chest radiographs of persons with pneumoconiosis. The aim has been to standardise classification methods and facilitate international comparisons of pneumoconiosis statistics and research reports. The ILO 1980 INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF PNEUMOCONIOSES is a further development towards this objective. It retains the same basic principles embodied in former editions of ILO classifications (i.e. those of 1950, 1958, 1968 and 1971 editions); it clarifies some ambiguities in the earlier texts; it consolidates advances made previously; and it introduces a few modifications which permit more detailed documentation of radiographic features characteristic of pneumoconiosis. The present classification covers the radiological appearances seen in all types of pneumoconiosis.

These improvements have been based on a careful review of international experience in the use of earlier classifications. The review involved active contributions of numerous experts, organisations and institutions at various national and international meetings. Particular recognition should be given to the work accomplished by the International Workshop on the ILO/UC 1971 Classification System, sponsored by the Task Force on Pneumoconioses of the American College of Radiology with the support of the National Institute of Occupational Safety and Health, U.S. Department of Health, Education and Welfare and with the co-operation of the ILO (Washington, D.C., September, 1978). A valuable contribution has been provided by the detailed technical discussions organised by the Working Group on Radiodiagnosis under the auspices of the Commission of European Communities in Luxembourg, London and Hasselt. At the Fifth International Pneumoconioses Conference, convened by the ILO in Caracas (Venezuela) from 29 October to 3 November 1978, a Working Group on Radiological Classification examined the final recommendations on the text of the revised classification and the selection of standard radiographs illustrating it.

The ILO 1980 Classification is accompanied by a new set of standard radiographs illustrating, and in some cases defining, the features described. The standard radiographs were selected following several controlled trials which involved more than 40 experts from different countries. The films include some that were distributed by the ILO in 1971, and others have been added. There has been no change in the level of profusion of small opacities depicted by the standards which now define the four main categories of profusion; but, with the assistance of the American College of Radiology, a greatly improved photocopying technique has been used to produce the films. The standard radiographs are now available from the ILO.

The intensive international activity which preceded publication of these guidelines has involved so many notable experts, institutions and organisations that it would be invidious to single out particular names, with one exception. Professor George Jacobson* died on 18 March 1979, a few days after making the last of his many vigorous contributions to the preparatory work on the classfication. The publication of this booklet is an appropriate occasion to record his devotion to the aims of the ILO Classification and to radiology of pneumoconioses.

The ILO extends its warm thanks to all concerned for their valuable assistance. The aim has always been to improve the understanding of pneumoconioses problems. The advances represented by the 1980 Classification are expected to further assist the continuing struggle to protect the health of workers occupationally exposed to airborne dusts.

*Dr. George Jacobson, Professor Emeritus, Department of Radiology, School of Medicine, University of Southern California, Los Angeles, USA; Chairman of the ILO Working Groups on Radiological Classification, Geneva, 1968, Bucharest, 1971 and Caracas, 1978.

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particular needs. For example, in coal workers' pneumoconiosis where pleural changes are relatively uncommon but a full classification of rounded opacities may be needed, it is possible to use the Complete Classification for the small opacities and the Short Classification for the pleural change.

In the interest of international comparability and to assist in the interpretation of publications on pneumoconiosis where this Classification is used, it is desirable to specify whether the Complete or Short Classification was employed; and also which set of standard radiographs was used. (Note 2).

Standard radiographs and written definitions

The Classification is based on a set of standard radiographs, a written text and a set of notes. In some parts of the scheme the standard radiographs take precedence over the text for the definitions; the text makes it clear when this is so. (Note 3).

GENERAL INSTRUCTIONS FOR THE USE OF THE CLASSIFICATION

There are no features to be seen in a chest radiograph which are pathognomonic of dust exposure. But the following recommendations are made for the classification of a postero-anterior radiograph:

1. if any of the appearances of the pleura or the parenchyma are consistent with pneumoconiosis, proceed with the Classification. Do not classify any appearances which are definitely not pneumoconiosis, but record these using Symbols and Comments (Note 4);

2. if it is probable that all the appearances seen are the result of some other aetiology, do not classify, but record opinion using appropriate Symbols and Comments (Note 4);

3. if the appearances might be due to pneumoconiosis, record the observations according to the Classification, but note also what other aetiology was considered.

COMPLETE CLASSIFICATION

Recording technical quality

Four grades of technical quality are used:-

1. Good.

2. Acceptable, with no technical defect likely to impair classification of the radiograph for pneumoconiosis.

3. Poor, with some technical defect but still acceptable for classification purposes.

4. Unacceptable.

If technical quality is not Grade 1, a comment should be made about the technical defects (Note 5).

Parenchymal abnormalities

Small Opacities

Profusion

The category of profusion is based on assessment of the concentration of opacities (Note 6) by comparison with the standard radiographs. For profusion the written definitions are a guide, but the standard radiographs take precedence (Note 7).

Category 0	-	small opacities absent or less profuse than the lower limit of category 1.
Categories 1, 2 and 3	-	represent increasing profusion of small opacities as defined by the corresponding standard radiographs.

By using the 12-point scale of profusion, the Classification recognises the existence of a continuity of change from no small opacities to the most advanced category. While still retaining the four major categories, 0, 1, 2 and 3, as defined by the standard radiographs, this scale readily permits subdivision into more categories and provides extra information. The instructions for using this 12-point scale are:- The radiograph is classified in the usual way into one of the four major categories by comparison with the standard radiographs. If during the process the major category above or below is seriously considered as an alternative, this is recorded. Thus, category 2/1 is profusion of major category 2, but with category 1 having been seriously considered as an alternative. Profusion which is without serious doubt category 2, that is, near the middle of the major category, should be classified 2/2.

In radiographs within category 0, a subdivision is also possible. Thus category 0/1 is profusion of category 0, but category 1 was seriously considered. Category 0/0 is a radiograph in which there are no small opacities, or if a few are thought to be present they are not sufficiently definite or numerous for category 1 to be considered. If the absence of small opacities is particularly obvious, the profusion should be recorded as 0/-. Within category 3 a radiograph showing markedly higher profusion than would be classified as 3/3 should be recorded as 3/+. Thus, the short four-point scale becomes the complete twelve-point scale: 0/-, 0/0, 0/1; 1/0, 1/1, 1/2; 2/1, 2/2, 2/3; 3/2, 3/3, 3/+. (Note 8). It must be emphasised that other abnormalities may be present regardless of the category of profusion of small opacities.

Extent

The zones in which the opacities are seen are recorded. The lungs are divided into six zones - upper, middle, and lower, right and left - by horizontal lines drawn at one-third and two-thirds of the vertical distance between the lung apices and the domes of the diaphragm.

The category of profusion of small opacities is determined by considering the profusion as a whole over the affected zones of the lung, and by comparing this with the standard radiographs. Where there is a marked (three minor categories or more) difference in profusion in different zones of the lung, then the zone or zones showing this marked lesser degree of profusion are ignored for the purpose of classifying the profusion (Note 9).

Shape and size

The shape and size (Note 10) of small opacities are recorded. Two kinds of shape are recognised: rounded and irregular. In each case, three sizes are differentiated. They are illustrated by standard radiographs which take precedence over the following written definitions. The letters p, q, r denote the presence of small rounded opacities, where

p = diameter up to about 1.5 mm;

q = diameter exceeding about 1.5 mm and up to about 3 mm;

r = diameter exceeding about 3 mm and up to about 10 mm.

The letters s, t, u denote the presence of small irregular opacities, where

s = width up to about 1.5 mm;

t = width exceeding 1.5 mm and up to about 3 mm;

u = width exceeding 3 mm and up to about 10 mm.

To record shape and size, two letters must be used. Thus if the reader considers that all or virtually all opacities seen are of one shape and size, then this should be noted by recording the symbol twice, separated by an oblique stroke (for example, q/q). If, however, another shape (or size) is seen, then this should be recorded as the second letter (for example, q/t). 'q/t' would mean that the predominant small opacity is round and of size q, but that there are significant numbers of small irregular opacities present of size t. In this way any combination of small opacities may be recorded (Note 11).

Standard radiographs illustrating both rounded and irregular shapes should be used for comparisons when the shape of opacity is in doubt or when both shapes are present.

Large Opacities

The examples of large opacities in the standard radiographs show abnormal opacities greater than 10 mm in diameter. The categories are defined in terms of dimensions of the opacities:

Category A - an opacity having a greatest diameter exceeding about 10 mm and up to and including about 50 mm, or several opacities each greater than about 10 mm the sum of whose greatest diameters does not exceed about 50 mm.

Category B - one or more opacities larger or more numerous than those in category A whose combined area does not exceed the equivalent of the right upper zone.

Category C - one or more opacities whose combined area exceeds the equivalent of the right upper zone.

Pleural abnormalities

Pleural Thickening

Site (chest wall, diaphragm, costophrenic angle), width and extent of pleural thickening are recorded separately and defined in the text below (Note 12).

Chest Wall

Types: Circumscribed (plaques), and/or diffuse (Note 12).

Site: Pleural thickening of the chest wall is recorded separately for the right and left chest walls.

Width: For pleural thickening seen along the lateral chest wall the measurement of the maximum width of the shadow is made from the inner line of the chest wall to the inner margin of the shadow seen most sharply at the parenchymal-pleural boundary. The maximum width usually occurs at the inner margin of the rib shadow at its outermost point.

a = maximum width up to about 5 mm.
b = maximum width over about 5 mm and up to about 10 mm.
c = maximum width over about 10 mm.

For pleural thickening seen face on (en face), the presence is recorded, even if it can also be seen in profile. If pleural thickening is seen face on only, width usually can not be measured.

Extent: Extent is defined in terms of the maximum length of pleural involvement, or as the sum of maximum lengths, whether seen in profile or face on.

1 = total length equivalent to up to one quarter of the projection of the lateral chest wall.

2 = total length exceeding one quarter but not one half of the projection of the lateral chest wall.

3 = total length exceeding one half of the projection of the lateral chest wall.

Diaphragm

A plaque involving the diaphragmatic pleura is recorded separately as present or absent, right or left. This is illustrated by an example in the standard radiographs (Note 13).

Costophrenic angle obliteration

The lower limit for this obliteration is defined by the standard radiograph showing profusion category 1/1 t/t. Such thickening is recorded separately from thickening over other areas (Note 14). If the thickening extends further up the chest wall, the radiograph should be classified as costophrenic angle obliteration and pleural thickening on the chest wall, if the latter is extent 1 or greater. Costophrenic angle obliteration is recorded as absent or present. The site, right or left, is specified.

Pleural Calcification

Site and extent are recorded for the two lungs separately. The following numerical definitions of extent take precedence over the examples in the standard radiographs (Note 15).

Site: Chest wall, diaphragm, and other. The latter includes calcification of the mediastinal and pericardial pleura.

Extent: 1 = an area of calcified pleura with greatest diameter up to about 20 mm, or a number of such areas the sum of whose greatest diameters does not exceed about 20 mm.

Extent: 2 = an area of calcified pleura with greatest diameter exceeding about 20 mm and up to about 100 mm, or a number of such areas the sum of whose greatest diameters exceeds about 20 mm but does not exceed about 100 mm.

3 = an area of calcified pleura with greatest diameter exceeding about 100 mm, or a number of such areas whose sum of greatest diameters exceeds about 100 mm.

Symbols

Symbols to record radiographic features of importance are listed below. Their use is obligatory. Examples are included in the standard radiographs and in the diagrams (Note 16).

It is to be taken that the definition of each of the Symbols is preceded by an appropriate word or phrase, such as "suspect", "changes suggestive of", "opacities suggestive of", etc.

The Symbols are:

ax - coalescence of small pneumoconiotic opacities (Note 16)

bu - bulla(e)

ca - cancer of lung or pleura

cn - calcification in small pneumoconiotic opacities

co - abnormality of cardiac size or shape

cp - cor pulmonale

cv - cavity

di - marked distortion of the intrathoracic organs

ef - effusion

em - definite emphysema

es - eggshell calcification of hilar or mediastinal lymph nodes

fr - fractured rib(s)

hi - enlargement of hilar or mediastinal lymph nodes

ho - honeycomb lung

id - ill defined diaphragm (Note 16)

ih - ill defined heart outline (Note 16)

kl - septal (Kerley) lines

od - other significant abnormality

pi - pleural thickening in the interlobar fissure or mediastinum

px - pneumothorax

rp - rheumatoid pneumoconiosis

tb - tuberculosis

The calcified primary complex of tuberculosis or other granulomatous processes, such as coccidioidomycosis or histoplasmosis should not be coded under tb. Such appearances should be noted under Comments.

Comments

Comments should be recorded pertaining to the classification of the radiograph, particularly if some other cause is thought to be responsible for a shadow which could be thought by others to have been due to pneumoconiosis; also to identify radiographs for which the technical quality may have affected the reading materially.

SHORT CLASSIFICATION

The detailed rules of how the Short Classification is to be used are as in the Complete Classification but with simplification. The details recorded are as follows:

Technical Quality

Technical quality is recorded 1, 2, 3 or 4 as for the Complete Classification (page 4).

Small Opacities

Profusion by comparison with standard radiographs into the four principal categories: 0, 1, 2 and 3 (page 4).

Shape and size by comparison of the predominant opacity pattern with standard radiographs.

If rounded, p, q or r.

If irregular, s, t or u as for Complete Classification (page 6).

Large Opacities

Category A, B or C as for Complete Classification (page 6).

Pleural Changes

Pleural thickening is recorded as symbol pt.
Pleural calcification is recorded as symbol pc.

Symbols

As for Complete Classification, together with pt and pc. All are obligatory (page 9).

Comments

Comments should be recorded as for Complete Classification (page 10).

EXPLANATORY NOTES

These notes are to assist in the understanding of the principles and use of the Classification. They do not take precedence over the written text but are intended to reduce ambiguities and differences in its use. They are based on experience with the previous Classifications.

Note 1 Scope

The Classification now covers all types of pneumoconiosis. It is designed for use with postero-anterior chest radiographs. This is not to say that other views should not be considered in the full clinical assessment of any individual.

Note 2 Standard Radiographs

The 1980 Classification is accompanied by a new set of standard radiographs which were selected after international trials. The trials were designed to obtain better illustrations of features described in the Classification.

Note 3 Definitions

In the past it has not been quite clear whether the standard radiographs or the text takes precedence in terms of definition. This is now clarified throughout.

Note 4 General Instructions

Comments must be recorded about appearances which are definitely or probably not pneumoconiosis. This may permit the resolution of apparent major discrepancies between readers.

Note 5 Technical Quality

It has been suggested that for epidemiological studies (when it may not be possible to replace a technically poor radiograph by a better one) more detail should be recorded about technical defects. In particular, if the parenchyma is visible and the pleura not, or vice versa, only part of a complete reading may be usefully available for statistical analysis. However, no specific recommendation about such recording is made at this time.

Note 6 Small opacities - order of recording

Profusion relates better than size to indices of exposure within any one occupational group. Since 1971 profusion has been recorded first.

Note 7 Standard radiographs for profusion of small opacities

Current research on the use of the Classification includes trials designed to test the validity and utility of additional standard radiographs for profusion. These are expected to illustrate (a) the boundary points on the continuum of profusion between the four major categories, and (b) the profusion characteristic of mid-categories, using only sections of the lung. The text describing the Classification has been prepared so that it may be used unchanged if trials are completed successfully and additional standard radiographs become available. (See also Appendix C).

In the Classifications from 1950 to 1971 the definitions in the text of the categories of profusion of small opacities included reference to the degree of obscuration of the normal vascular pattern of the lung - no obscuration in Category 1, sometimes and partially in Category 2, and usually, partly or totally in Category 3. In the 1980 Classification this information is omitted in the text but will be apparent from inspection of the standard films. The degree of obscuration may be of assistance in deciding the category of small opacities.

Note 8 Twelve-point scale for profusion of small opacities

The twelve categories of the complete Classification represent divisions on a continuous scale of profusion of small opacities. In practice it is no more difficult to use than the four categories of the short Classification. On the contrary, most readers find that the 12-point scale is helpful because it enables them to codify the appearances of radiographs that are not obviously similar to the standards. For instance, categories 0/1 and 1/0 may be used to represent "suspect" pneumoconiosis.

The twelve categories range from an exceptionally "normal" radiograph at one end of the scale (0/-) to an advanced Category 3 at the other (3/+). The intermediate ten categories are arbitrary divisions of increasing profusion between these two extremes. The concept of a continuum of radiological abnormality is consistent with results from extensive epidemiological research on relationships between radiological classifications and (a) cumulative dust exposures, and (b) the dust content of post-mortem lungs; it is supported also by studies of the variability between different readers' classifications of the same radiographs.

Note 9 Determining profusion over different zones

Classification of a radiograph for profusion of small opacities requires a mental process of integrating profusion over the affected zones. Earlier Classifications referred to this process as "averaging". This might be confused with arithmetical averaging of the numbers which symbolise the categories. Therefore the word "averaging" is not used in the 1980 Classification.

Note 10 Shape and size of small opacities

The 1980 Classification distinguishes between the concepts Shape and Size of small opacities. The symbols used are the same as those defined in previous Classifications under the general heading Type.

For small opacities shape and size are both known to be important. For example, in coalworkers' pneumoconiosis, profusion of p and q opacities relates better to dust content of the lung than the profusion of size r opacities. Also men with small p opacities tend to have lower values of gas transfer of carbon monoxide. Asbestos workers with a "u" pattern have worse prognosis.

Note 11 Mixtures of shapes and sizes

The 1980 Classification permits recordings of mixtures of shapes and sizes of small opacities on the same radiograph. When, as usually occurs, only one shape (and size) is seen, the symbol denoting that shape and size must be recorded twice on the reading sheet (for example, record p/p when only small rounded opacities of size p are seen). This rule avoids ambiguities on the written records and emphasises that not all radiographs with small opacities show mixtures of shapes.

Note 12 Pleural Thickening

Shadows are produced by thickening of the visceral and parietal layers of the pleura. Confident identification of which surface is thickened may not always be possible using the postero-anterior radiograph. But separation may be useful because there may be differing aetiologies, natural histories and relations to disability.

Pleural thickening occurs in two principal forms, the different appearances of which are illustrated in the standard radiographs. Both types may occur together. Separation of the two types is usually, but not always possible. In some cases small peripheral shadows of indeterminate type occur.

(a) Circumscribed shadows (non-calcified hyaline plaques)

The standard radiographs include an example of the characteristic appearance of these shadows. They are normally the result of thickening of the parietal pleura, and are the precursors of calcified plaques.

The extent of these shadows in relation to the length of the lateral chest wall provides a rough measure of their size. But a postero-anterior radiograph may reveal only a small proportion of their full extent. The width of the shadow measured between the inner edge and the chest wall is highly influenced by the precise position of the plaque on the chest wall, so that this measurement may not be an indication of severity.

(b) Diffuse shadows

The standard radiographs include examples of the appearances of these shadows. This is the well recognised type of pleural thickening seen also in many non-pneumoconiotic conditions. It is probably the result of thickening of the visceral pleura. It is less specific to asbestos and other fibrous mineral dust exposure, but it is a feature in some cases of severe asbestosis. The word 'diffuse' refers to the tendency to produce a general veiling of lung parenchymal detail. In some cases the shadow produces a sharply defined line along the chest wall due to it being seen in profile (edge on). When this appearance is well developed the maximum width of the shadow is recordable. The extent is recorded as for circumscribed shadows. These two measurements may provide the best index of the severity of visceral pleural involvement.

Note 13 Diaphragm

Circumscribed thickening (plaque) of the diaphragmatic pleura is considered by some as highly specific to exposure to asbestos and other fibrous dusts. The shadows are identifiable most easily when shaped like a crater. Diffuse thickening is less specific to past dust exposure and accompanies costophrenic angle obliteration. If it is extensive, it should be recorded using the symbol id (see Note 16).

Note 14 Costophrenic angle obliteration

This is recorded separately from other pleural thickening because it frequently occurs, at least unilaterally, in those not exposed to asbestos or other dust. Costophrenic angle obliteration is, however, of special relevance in asbestos exposed people. "Leafing" of the diaphragm should not be recorded as filling of the angle even though it leads to obscuration of the costophrenic angle.

Note 15 Pleural calcification

Pleural calcification may be due to trauma, old infections, or exposure to asbestos, talc and some other minerals. The mineral dusts tend to produce bilateral changes. The calcification varies from just detectable spicules a few millimetres long to large areas covering nearly the whole lung. The large plaques have "rolled" edges and have been likened in appearance to holly leaves or candlewax.

Note 16 Symbols

It is highly desirable that the reading sheet should contain the full list of Symbols, as it is only by doing this that a check can be made of the completeness of recording. Failure to use all the Symbols and Comments in statistical analyses is likely to lead to unnecessary unexplained differences between observers.

Attention is drawn to the following points.

The Symbol ax (coalescence of small opacities) may be recorded in the presence of large opacities.

The Symbol id (ill-defined diaphragm) should only be recorded if more than one-third of one hemidiaphragm is affected.

The Symbol ih (ill-defined heart outline) should only be recorded if the length of border affected is more than one-third on the left cardiac border.

USING THE CLASSIFICATION

Efficient use of the Classification requires good viewing and recording conditions. It is assumed that readers have good vision (with the aid of spectacles if necessary). The following recommendations are particularly important for epidemiological studies.

Viewing

The viewing boxes on which the radiograph to be classified and the standards are to be displayed need to be near enough for the observer to see shadows only 1 mm in diameter, that is about 250 mm distance, but it must also be possible to view the whole radiograph from about twice this distance. The observer should be seated and not have to lean uncomfortably far forward to view the radiograph closely. (In some departments of radiology the viewing boxes are too far from the edge of the table to provide satisfactory conditions.)

The minimum number of viewing spaces on a viewing box is two and the optimum probably five. It is recommended that the radiograph to be classified is placed in the middle, and the more commonly used standard radiographs on either side. Whatever the arrangement, it is important to make it easy to select and put up the standard radiographs for comparison. Failure to do this discourages readers from regular use of standards, and this is thought to be one of the causes of inter-observer variability.

The viewing boxes must be clean. The intensity of illumination should be uniform over the whole surface and visually identical over the areas where the comparisons are being made. A pair of well matched single viewing boxes is adequate but a longer box, about 1600 mm x 400 mm is preferable.

(A box with two standard sized 1500 mm colour matched 80w fluorescent tubes mounted 100 mm behind an opal plastic screen 3 mm thick will give a very uniform and well illuminated screen of 1600 x 400 mm to hold four 400 x 400 mm radiographs.)

The general illumination in the room should be low without direct daylight. The room should be quiet, comfortable and free from distractions.

Epidemiological reading protocols

When classifying radiographs for epidemiological purposes it is essential that the reader does not consider any information about the individuals concerned, other than the radiographs themselves. Awareness of supplementary details specific to individuals can introduce bias into results. If the epidemiological objective is to make comparisons between two or more groups, then the radiographs from all groups should be mixed, and presented to the reader in random order. Failure to observe these principles may invalidate conclusions from the study.

Recording

Recording of results should be standardised and systematic. If the results are to be analysed with the help of a computer then the proforma should be designed accordingly. In all cases, it is important to make provision for recording definitely the absence of any feature not seen, and whether or not any Comments are being made on the radiograph concerned. This avoids ambiguity in the interpretation of blanks on the pro-forma. Clerical help for recording results is valuable when classifying large numbers of radiographs. The assistant should then be asked to remind the reader of failure to report the presence or absence of any feature included on the pro-forma.

Reading rates

The number of radiographs classifiable per unit time can vary greatly. Factors influencing reading rates include the prevalence of abnormalities on the radiographs, their technical quality, the experience of the reader, the purpose of the reading exercise, and the length of the reading session. Some readers can work comfortably for two or two-and-a-half hours with no break. With clerical help they may classify several hundred radiographs in that time if the abnormality rate is low. Others prefer to arrange their work as a series of shorter sessions (perhaps one or one-and-a-quarter hours each), with intervals for rest.

Number of readers

It is recognised that there is considerable variation in repeated readings of the same radiograph, not only from reader to reader, but also between readings by the same reader. It is strongly recommended that at least two, and preferably three independent readings are made for each radiograph.

When many radiographs are being read, intra-observer variation (that is, variation in repeated readings by the same reader) should also be assessed.

APPENDICES

These have been prepared by various experts to assist understanding of the principles and development of the Classification. Some of the views expressed may be controversial. The Appendices are not a part of the text of the ILO 1980 INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF THE PNEUMOCONIOSES.

APPENDIX A

EQUIPMENT AND TECHNOLOGY : GUIDANCE NOTES*

It has long been recognised that the exposures received by radiographs of the chest have a marked influence on the radiographic appearance of lesions of pneumoconiosis. Consequently, readers of radiographs which demonstrate evidence of pneumoconiosis will find difficulty in applying the ILO 1980 Classification for reporting the characteristics of this disease unless the exposures used in making the radiographs are maintained within an optimum range. Application of the system will only be as satisfactory as radiographic technical quality is good.

The importance of image density and radiation exposure to technical excellence in chest radiography is difficult to over-emphasise. It is known that by far the greatest causes of poor technical quality in chest radiographs (well over ninety percent) are over-exposure and under-exposure, unsatisfactory gross image contrast, poor screen-film contact and fog. Medical training should include the fundamentals of radiographic technique so that physicians are able to determine the causes of poor technical quality when encountered. Some technologists work without adequate supervision by knowledgeable physicians, and, until recently, convenient densitometric instruments have not been available with which the quality of each radiograph can be measured at the time it is made.

What is clearly needed are (1) improved training programmes in radiographic technology for both physicians and technologists; (2) closer liaison between physicians and technologists in

* Prepared by H. Bohlig, Y. Hosoda, G. Jacobson (deceased) and R. Morgan.

day-to-day practice, and (3) widespread use of the recently available pocket densitometers to determine the technical quality of each chest radiograph when it is made.

Using subjective criteria, the most desirable chest radiograph for the detection of abnormalities of the pneumoconioses is one in which the pulmonary parenchymal markings are shown in greatest detail, the costopleural junctions are clearly seen, and the major pulmonary vessels are visible through the cardiac shadow. While it is important to visualise the details of the mediastinal structure as well, this is usually not possible on a radiograph made for assessment of pneumoconiosis.

On physical grounds, a radiograph of satisfactory technical quality may be defined as one in which the exposure has been such that the optical densities of the images of interest fall between 0.3 and 1.7 and in which the difference in optical density between the darkest image of interest and the lightest is 1.0 or more. The inherent contrast (i.e. the density vs log exposure gradient) of radiographs falls off rapidly as optical densities descend below 0.3 and hence, image quality becomes increasingly unsatisfactory as this occurs. Above an optical density of 1.7, the inherent contrast of radiographs remains good but extraneous light entering the observer's eyes from light sources other than the x-ray viewing boxes tends to impair the contrast of the radiographic image when projected on the retinae. Hence, technical quality deteriorates for images having optical densities much above 1.7 density units. (See also Appendix C, paragraph 8).

Equipment

The installation and maintenance of the radiographic equipment is of the greatest importance. The electric power source should be independent of other users. It must be of adequate capacity, for example, having a resistance of not more than 0.1 Ω and should be subject to no more than 5 per cent fluctuation. The voltage drop between the main supply and the x-ray unit when the unit is at its maximum output should not exceed 10 per cent. The radiographic unit must be carefully calibrated at the time of installation and should be recalibrated periodically. Preventive maintenance at regular intervals is strongly recommended.

The generator should have a minimum capacity of 300 mA at 125 kV. The generator must be full-wave rectified. It should be equipped with an accurate timer ($\pm$ 1 per cent) capable of minimum exposure of no more than 10 ms. Ideally, three-phase generators should be used for both fixed and mobile units. However, in the case of mobile units, when it may not be feasible to use three-phase generators, condensor-discharge units may be the apparatus of choice.

A rotating anode tube is essential. It should have as small a focal spot as feasible for the anticipated load, but in no instance should this exceed 2 mm in diameter.

The total filtration, added and inherent, of the primary x-ray beam should be the equivalent of 2 mm of aluminium.

The radiation should be confined by means of a collimator to the portion of the subject to be examined. This will not only decrease radiation hazard, but also will improve detail by reducing scattered radiation. The collimator should have adjustable diaphragms, a light beam for centring, and be designed so that the projected field cannot exceed the size of the film. Evidence of collimation should be visible at the edges of the film as "cone cuts".

Medium speed (par speed) intensifying screens should be used. They provide the best compromise between sharp definition and short exposure. The cassettes in use should contain screens of the same speed. Both films and screens should be tested and matched for speed, and cassettes should be checked periodically for screen cleanliness, contact and defects.

The x-ray film should be of a general purpose type and of medium sensitivity. High speed film is not recommended. To improve collimation, the film should be no larger than needed to cover both lungs, including the costophrenic angles.

When using kilovoltages of 80 and above, reduction of secondary radiation by a grid or other means is essential. A 10:1, 100-line per inch fixed grid or an air-gap of 200 mm with a 2.5 m focal spot-film distance may be used.

Automatic processing should be employed whenever possible. If only manual processing is available, a constant time-temperature technique must be followed meticulously. An improper exposure cannot be corrected by improper processing.

Technique

Correct centring of the x-ray tube and careful positioning of the subject are of great importance for the proper visualisation of anatomic structures and comparison of serial examinations. For the PA projection, the x-ray tube should be centred to the centre of the film and the x-ray beam directed horizontally. The shoulders should be positioned so that the scapulae are outside the lung fields. The exposure should be made at full inspiration and immediately after this has been reached, to avoid the Valsalva effect. It is desirable, but not essential, that all the clothes above the waist be removed.

The focal spot-film distance should be fixed at 1.8 m (6 feet) and should not be less than 1.5 m (5 feet).

For reasons given above, a variable high kilovoltage, constant milliampere-second technique is recommended. Exposure factors employed may vary somewhat with each generator and tube. The highest range of kilovoltage and shortest range of milliamperes-seconds obtainable should be used. For the average subject, with an AP chest diameter between 210 and 230 mm, the usual exposure factors will be 5 mAs at approximately 125 kV. The recommended exposure time is 1/60 (0.017) s; not exceeding 1/30 (0.03) s. (Based on 60 Hz current. For 50 Hz current, exposure times are 1/50 (0.02) and 1/25 (0.04) s respectively.)

With larger diameters of the chest, additional exposure is obtained by increasing the kilovoltage. The milliampere-second product is increased only when the kilovoltage required to give a proper exposure exceeds the capability of the generator or x-ray tube. With focal spot-film distances of less than 1.8 m (6 feet) the technique should be adjusted by decreasing the milliampere-second product.

When using a lower kilovoltage technique, the exposure factors for an average subject will be approximately 300 mA, 0.05 s (15 mAs) at 75 kV. For larger subjects, greater amounts of radiation are obtained by increasing either the milliampere-second product or the kilovoltage.

It is recognised however that the question of optimal radiographic technique remains a controversial matter among experts internationally.

Physical criteria for excellence of technical quality in chest radiographs

A. Optical density

1. Hilar regions should exhibit a minimum of 0.2 units of optical density above fog.

2. Parenchymal regions should exhibit a maximum of 1.8 units of optical density above fog.

B. Gross image contrast* should fall within the range of 1.0 and 1.4 units of optical density.

C. X-rays tube potentials and use of grids

1. Potentials of 70 to 100 kVp: use grids for all subjects whose posteroanterior dimension exceeds 220 mm.

2. Potentials over 100 kVp: use grid for all subjects.

D. Exposure time

Not greater than 0.1 s, and preferably 0.05 s or less.

E. Film-screen combination

Use medium-speed films and screens to assure adequate image detail. Good screen-film contact is essential with periodic testing mandatory.

F. Processing

Maintain strength and temperature of processing chemicals within limits recommended by manufacturer.

G. Assumptions

1. Cleanliness of films and screens and of processing fluids and equipment is maintained.

2. Care in subject positioning is taken.

3. Subject movement is prevented.

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* The difference in optical density between the darkest segment of the lung parenchyma and the lightest portions of the hilar regions.

APPENDIX B

CHANGES FROM THE ILO U/C 1971 CLASSIFICATION*

Title and Scope

U/C is omitted from the title. This stood for UICC/Cincinnati and was included in the 1971 title to draw attention to its incorporation of the UICC/Cincinnati 1970 Classification devised to cover asbestosis which was not covered in the ILO 1968 scheme. The Classification now covers all types of pneumoconiosis so reference to specific types is no longer necessary.

Object and Uses of the Classification

These have been separated and slightly modified.

General Instructions

The wording has been clarified and a reminder is added to record other conditions not thought to be due to pneumoconiosis. This additional information in the Symbols and Comments can assist in resolving some discrepancies between observers.

Recording Radiographic Quality

This is now formally part of the Classification. This permits comparisons of the general quality of radiographs in different surveys. It also allows exclusion from analysis of data referring to radiographs of quality too poor to permit satisfactory classification.

Use of Standard Radiographs

In earlier versions of the Classification it was not always clear whether the appearances to be classified were defined primarily by the standard radiographs or by the text which describes the system. The 1980 Classification states specifically, for each feature, which method of definition has precedence and which should be regarded as providing supplementary information.

* Prepared by J.C. Gilson and C.E. Rossiter.

Profusion of small opacities

The degree of obscuration of the normal vascular pattern is no longer included as part of the definition of small opacities as profusion is now defined by comparison with the standard radiographs. However, it is included in Note 7.

Profusion and Type (Shape)

Experience using the 1971 scheme has shown that while some radiographs are classified consistently by all readers as 'rounded' and others as 'irregular', there are many radiographs for which some readers record 'rounded' and others 'irregular'. There are also radiographs where both types are recorded. This has caused serious difficulties in interpretation and analysis.

The 1980 Classification provides a means of reducing these difficulties and obtaining more information without loss of continuity with the 1971 scheme and without the introduction of new standards or definitions of the types of opacities.

Profusion

In the 1971 scheme recording of combined profusion was optional. In the 1980 scheme a single measure of profusion is recorded first using the appropriate standard radiographs. This places emphasis on the usually more important index, because the profusion of small opacities relates much better to intensity of past dust exposure than does the type of opacity.

The twelve-point scale for measuring profusion is retained unaltered except that the symbol 3/+ replaces the earlier symbol 3/4. (There is no category 4.)

The wording of the method used for deciding on the category of profusion has been amended to remove any suggestion that arithmetical averaging of profusion in different zones is required.

Type (Shape and Size)

In the 1971 Classification the Type referred to a complex of shape (roundness or irregularity) of the opacity and its size. Type and size were defined by standard radiographs and for rounded opacities (p, q, r) by an approximate measurement of the diameter (up to 1.5 mm; 1.5 - 3 mm; up to 10 mm). Dimensions for the irregular opacities were not provided but it was intended in the UICC/Cincinnati 1970 Classification that s, t, u irregular opacities should approximately 'match' the p, q, r rounded opacities for size.

In the 1980 scheme shape and size are defined by the standard radiographs using the same letters p, q and r for rounded opacities and s, t and u for irregular opacities. However, in the text s, t and u are given approximate sizes, in terms of width of opacity, to formalise the match of the rounded opacities:

s = width up to about 1.5 mm.

t = width exceeding 1.5 mm and up to about 3 mm.

u = width exceeding 3 mm and up to about 10 mm.

It is required to use two of the letters describing shape and size, thus providing a means for recording systematically the shape and size of small opacities which are a mixture of rounded and irregular. As two letters have to be used, a repetition of the same letter affirms positively that the opacities are all or predominantly of one shape and one size.

Rounded and irregular opacities clearly have different significance in relation to the type of mineral dust to which exposure has occurred. For example, coal produces mainly rounded opacities and asbestos mainly irregular. Future research will show whether the degree of roundness - irregularity relates to prognosis in minerals producing a mixed pattern.

In summary: the 1980 scheme provides for recording a single measure of profusion on a 12-point scale and for recording opacities of different shapes and/or sizes, while retaining a high measure of comparability with the 1971 scheme.

Large Opacities

No changes are made in the definition of A, B and C, but the qualifying words well defined (wd) and ill defined (id) are no longer used.

Pleural abnormalities

These are now recorded separately right (R) and left (L). This was recommended because in practice each is assessed separately and the recording of the two independently provides more information for no extra effort.

Thickening; Chest Wall

Type

Pleural thickening is divided into two types, circumscribed (plaques) and diffuse, and their appearances are exemplified in the standard radiographs.

Width

The definitions have been slightly altered to bring them in accord with other dimensions in the classification. The word 'grade' is omitted. It is also made clear that the width is measured from the inner line of the chest wall to the inner margin of the shadow seen most sharply at the parenchymal-pleural boundary (the cross-sectional width) and not its less well defined edge extending over the surface of the lung. The classification also requires the presence of pleural thickening seen face on to be recorded even if the width can not be measured.

Extent

An extra subdivision of extent has been included to provide more information about lesser changes. The word 'grade' has been omitted. Pleural thickening seen face on is included in the assessment of extent:

1. total length equivalent to up to one quarter of the projection of the lateral chest wall;

2. total length exceeding one quarter but not one half of the projection of the lateral chest wall;

3. total length exceeding one half of the projection of the lateral chest wall.

In the 1971 scheme it was not clear whether pleural thickening on the diaphragm - pleural plaques - should be added to that on the chest wall in assessing extent. In the 1980 scheme they are specifically excluded from the assessment of extent, but their presence is recorded.

Ill-defined Diaphragm and Cardiac Outline

These are no longer recorded in the main Classification but their presence noted without grades or lower limit standards in the Symbols, but using as lower limits the definitions in the 1971 Classification.

They were omitted from the main Classification because of their relatively low prevalence and great rarity as the sole evidence of exposure to dusts.

Symbols

The use of all Symbols is now obligatory. All are now two letters only to facilitate recording and computing. The additions and modifications are:

fr = fractured rib(s)

id = ill defined diaphragm

ih = ill defined heart outline

kl = septal (Kerley) lines - previously k

pi = thickening of interlobar fissure

rp = rheumatoid pneumoconiosis - previously rl

tb = tuberculosis (excluding primary focus). This replaces tba and tbu.

Comments

Comments were optional in previous Classifications. They should now always be added; for example, when there are technical faults making it difficult or impossible to classify the films adequately; also when there are features which might be included or excluded in the Classification by other observers. Thus, causes of big observer variation might become identifiable.

APPENDIX C

RECOMMENDATIONS FOR FUTURE RESEARCH*

Discussions at the meetings of experts which advised the ILO on the preparation of the 1980 Classification were based on wide experience in the use of earlier versions of the Classification. The experts identified several areas where additional information would be expected to lead to further improvements. Recommendations for continuing research on the classification of radiographic appearances of the pneumoconioses included the following.

1. Assessment of the 1980 Classification

Changes in the present (1980) Classification, as compared with the ILO U/C 1971 Classification, have been summarised in Appendix B. Quantitative studies aimed at describing the effects of changes in the procedures will assist interpretation of future pneumoconiosis statistics and research reports. Whenever possible, designs for such studies should be specific to particular changes that have been adopted.

2. Standard "boundary" radiographs

The 1980 standard radiographs show patterns of profusion of small opacities which are typical of appearances classifiable as near the middle of the four main categories defined by the scheme (so-called "mid-category standards"). It is possible that classification might be easier, and that precision would be increased, if there were available standard radiographs which define the three boundaries between the four main categories. The existence of such "boundary standards" would constitute an improvement in the definitions of categories of profusion, and would be particularly useful in helping to distinguish between categories 0/1 and 1/0. Some experts feel that, in the first place, research on the usefulness of boundary radiographs should be concentrated on this region of the continuum of abnormality.

International trials which preceded the selection of the 1980 set of "mid-category standards" identified several radiographs which might be regarded as "boundary standards": expert opinion was divided fairly evenly on whether they

* Prepared by J.C. Gilson and M. Jacobsen

should be classified into one or the other sub-category adjacent to a boundary between two main categories. It is desirable to continue research on boundary standards to get better knowledge on how they are to be used. Each experimental set will be accompanied by suggestions on how they may be used and tested.

3. Sectional and composite standard radiographs

Some readers find that the present standard radiographs are inconvenient in practice because of their size and number. There have been experiments with small copies of sections of standard radiographs, and with composite reproductions of these copies. It is recommended that this work should continue. Tests are required to determine the optimal area for a section and to assess the effects of using such standards rather than the present set.

4. Profusion of small opacities

The 1980 Classification requires that the profusion of small opacities should be determined by comparison with the standard and by integrating the profusion seen over the affected zones of the lung. It includes provision for indicating which of (six) zones are affected. It may be easier, and more reproducible, to record profusion separately for each of the four quadrants of the lung. Composite standard radiographs incorporating images of the four quadrants might assist such a change in procedure. It is recommended that the suggested change in the method for recording profusion might be tested in parallel with research on the production of composite standard radiographs.

5. Large opacities

Several reports indicate surprisingly poor between-reader agreement in recording the presence of large opacities. Identification and systematic documentation of the reasons for such inconsistency would be valuable.

6. Pleural thickening

It is difficult to distinguish clearly between abnormal thickening of the parietal and visceral layers of the pleura, and there are problems of nomenclature. Yet the distinction may be important pathologically, and it is thought by some to have aeteological significance. Further consideration needs to be given to how to improve the method for recording radiological evidence of pleural abnormalities. (See also Note 12.)

7. Shape and size of small opacities

The 1980 Classification clarifies the difference between the concepts shape and size of small rounded opacities. There is provision also for recording the presence of mixtures of shapes (and sizes). This opens the way for further research on the prognostic and aetiologic significance of different combinations of shapes. The new convention will also facilitate studies of whether different sizes of small irregular opacities represent real pathological distinctions or whether they are merely radiological reflections of different degrees of profusion of the smallest lesions recognisable as irregular opacities.

8. Technical quality of radiographs

The present system for recording technical quality does not include a standardized notation to indicate the nature or suspected cause of the inadequacies observed. Yet it is known that readers differ in their assessments of quality, and that their assessments affect their classifications. More studies are required to determine the way in which different imperfections influence readers' use of various parts of the Classification, and on how their judgement of quality can be recorded in a standard way. Use of quantitative measurements of film density may provide an objective index to assist quality assessments. This could lead to raising radiographic standards and to a better understanding of factors influencing subjective assessments of radiographic quality.

9. Non-pneumoconiotic shadows

The General Instructions for the use of the 1980 Classification (page 3) preserves the principle from earlier Classifications that radiographic appearances regarded as "definitely not pneumoconiosis" are not to be classified; but the use of Symbols and Comments are now obligatory in such cases. Differences between readers in what they regard as "definitely not pneumoconiosis" and "probably the result of some other aetiology" should be studied.

Some experts believe that application of the Classification for epidemiological purposes would be more objective if the descriptive notation defined by the Classification were used in all cases where the shadows seen are consistent with the appearances of the standard radiographs and the definitions in the text (pp. 4 to 10), irrespective of whether the appearances are thought to be due to pneumoconiosis. Obligatory use of Symbols and Comments would ensure that a reader's opinion that the shadows classified are not due to dust exposure would be recorded and available for statistical analysis. It is recommended that research should continue on this matter.

APPENDIX D

READING SHEET

The section on USING THE CLASSIFICATION (pp 18 to 20) gives guidance on the conditions and procedures which are particularly important for epidemiological studies involving the radiology of the pneumoconioses. An example of a reading sheet which may be used to record systematically all the information required by the Complete Classification is provided as a further aid. The word example is emphasised. Alternative designs may often be appropriate for particular applications.

The sheet illustrated can be used easily to transfer data into a form suitable for machine processing. If this intended then it will be helpful to use capital letters (rather than lower-case letters) to record all features and Symbols. Permissible symbols are indicated in brackets (   ), using lower-case letters consistent with the text describing the Classification.

The letters Y and N are used on the sheet to represent the words "Yes" and "No". Alternative symbols may be desirable if reading sheets are prepared in languages other than English.

Note that there may be no blanks to the right of the dashed line. This provides a useful visual aid to verify that a radiograph has been classified properly before it is removed from the viewing box.

* Prepared by M. Jacobsen and C.E. Rossiter.

READING SHEET

* suitable for use with the ILO 1980 INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF THE PNEUMOCONIOSES

IDENTIFICATION DATA

FILM

READER

READING DATE

FILM QUALITY	Grade (1, 2, 3, 4)	
	Comment made (Y, N)	
SMALL OPACITIES	Profusion (12-point scale)	
	Extent (√ appropriate zones)	R L
	Shape and size (2 of p,q,r,s,t,u; or repeated symbol)	
LARGE OPACITIES	Presence (Y, N)	
	Size (A, B, C)	
PLEURAL THICKENING CHEST WALL – CIRCUMSCRIBED [PLAQUES]	Presence (Y, N)	R L
	Face on (Y, N)	
	Width (a, b, c)	
	Extent (1, 2, 3)	
– DIFFUSE	Presence (Y, N)	
	Face on (Y, N)	
	Width (a, b, c)	
	Extent (1, 2, 3)	
DIAPHRAGM	Presence (Y, N)	
	Site (√ site)	
COSTOPHRENIC ANGLE OBLITERATION	Presence (Y, N)	
	Site (√ site)	
PLEURAL CALCIFICATION	Presence (Y, N)	R L
CHEST WALL	Site (√ site)	
DIAPHRAGM	Site (√ site)	
OTHER	Site (√ site)	
	Extent (1, 2, 3)	
SYMBOLS	Used ? (Y, N)	
up to 6† from	ax bu ca cn co cp cv di ef em es fr hi ho id ih kl od pi px rp tb	
(† Record further symbols in COMMENTS section)		
COMMENTS (Write comments)	Made ? (Y, N)	

*NO BLANKS ARE PERMISSIBLE TO THE RIGHT OF THE DASHED LINE

APPENDIX E

DESCRIPTIONS OF STANDARD RADIOGRAPHS*
(1980 Revision)

The standard radiographs accompanying the ILO 1980 International Classification of Radiographs of the Pneumoconioses consist of 22 films.

Two radiographs illustrate the appearance classifiable as category 0/0 for profusion of small opacities.

Eighteen radiographs depict appearances classifiable as categories 1/1 through 3/3 for profusion and p/p through t/t for shape and size of small opacities and as categories A through C for size of large opacities. Descriptions of these radiographs are given in the accompanying tables, with notation defined in the Classification and with additional Comments as appropriate. The site of small opacities is shown by a tick in the boxes symbolizing the zones of the lungs as follows:

	Right	Left
Upper		
Middle		
Lower		

The two remaining radiographs are composite reproductions of sections. One depicts the increasing profusion of irregular small opacities of size "u". The other illustrates various types of pleural abnormality.

Note that the Technical Quality of eight of these radiographs has been judged as meriting grade 2 only. This is because the international trials which preceded the selection of the 1980 set of standards did not yield any better quality examples of the features concerned.

* Prepared by C. Amoudru, H. Bohlig, J.A. Dick, J.C. Gilson, A. Minette and R. Morgan

DESCRIPTIONS OF STANDARD RADIOGRAPHS

1980 STANDARD RADIOGRAPHS SHOWING	TECHNICAL QUALITY	SMALL OPACITIES: PROFUSION	SMALL OPACITIES: SHAPE-SIZE	SMALL OPACITIES: EXTENT	LARGE OPACITIES	PLEURAL THICKENING: CHEST WALL: CIRCUM-SCRIBED (PLAQUES)	PLEURAL THICKENING: CHEST WALL: DIFFUSE	PLEURAL THICKENING: DIAPHRAGM	PLEURAL THICKENING: COSTOPHRENIC ANGLE OBLITERATION	PLEURAL CALCIFICATION	SYMBOLS	COMMENTS
0/0 (example 1)	1	0/0	-	-	No	No	No	No	No	No	None	Vascular pattern is well illustrated.
0/0 (example 2)	1	0/0	-	-	No	No	No	No	No	No	None	Also shows vascular pattern, but not as clearly as example 1.
1/1; p/p	1	1/1	p/p	R L: ✓✓ / ✓✓ / ✓✓	A	No	No	No	No	No	rp.	Rheumatoid pneumoconiosis in left lower zone. Small opacities are present in all zones, but the profusion in the right-upper zone is typical of (some would say a little more profuse than) that classifiable as category 1/1.
2/2; p/p	2	2/2	p/p	R L: ✓✓ / ✓✓ / ✓✓	No	No	No	No	No	No	pi; tb.	Quality defect: radiograph is too light.
3/3; p/p	1	3/3	p/p	R L: ✓✓ / ✓✓ / ✓✓	No	No	No	No	Yes R L: ✓ –	No	ax.	None
1/1; q/q	1	1/1	q/q	R L: ✓✓ / ✓✓ / – –	No	No	No	No	No	No	None	Illustrates profusion 1/1 better than shape or size.
2/2; q/q	1	2/2	q/q	R L: ✓✓ / ✓✓ / ✓✓	No	No	Yes R L: ✓✓ Width: a a Extent: 1 1	No	Yes R L: ✓✓	No	None	None

DESCRIPTIONS OF STANDARD RADIOGRAPHS (continued)

1980 STANDARD RADIOGRAPHS SHOWING	TECHNICAL QUALITY	SMALL OPACITIES			LARGE OPACITIES	PLEURAL THICKENING				PLEURAL CALCIFICATION	SYMBOLS	COMMENTS
		PROFUSION	SHAPE-SIZE	EXTENT		CHEST WALL: CIRCUM-SCRIBED (PLAQUES)	CHEST WALL: DIFFUSE	DIAPHRAGM	COSTOPHRENIC ANGLE OBLITERATION			
3/3; q/q	2	3/3	q/q	R L ✓ ✓ ✓ ✓ ✓ ✓	No	No	No	No	No	No	pl.	Quality defects: poor definition of pleura and cut basal angles.
1/1; r/r	2	1/1	r/r	R L ✓ ✓ ✓ ✓ – –	No	No	No	No	Yes R L – ✓	No	None	Quality defect: subject movement. Profusion of small opacities is more marked in right lung.
2/2; r/r	2	2/2	r/r	R L ✓ ✓ ✓ ✓ ✓ ✓	No	No	No	No	No	No	None	Quality defects: radiograph too light and contrast too high. The heart shadow is slightly displaced to the left.
3/3; r/r	1	3/3	r/r	R L ✓ ✓ ✓ ✓ ✓ ✓	No	No	No	No	No	No	ax; ih.	None
1/1; s/t	2	1/1	s/t	R L ✓ – ✓ ✓ ✓ ✓	No	No	No	No	No	No	kl.	Quality defect: cut bases. Kerley lines in lower right zone.
2/2; s/s	2	2/2	s/s	R L – – ✓ ✓ ✓ ✓	No	No	No	No	No	No	em.	Quality defect: distortion of bases due to shrinking. Emphysema in upper zones.

DESCRIPTIONS OF STANDARD RADIOGRAPHS (continued)

1980 STANDARD RADIOGRAPHS SHOWING	TECHNICAL QUALITY	SMALL OPACITIES: PROFUSION	SMALL OPACITIES: SHAPE-SIZE	SMALL OPACITIES: EXTENT	LARGE OPACITIES	PLEURAL THICKENING: CHEST WALL: CIRCUMSCRIBED (PLAQUES)	PLEURAL THICKENING: CHEST WALL: DIFFUSE	PLEURAL THICKENING: DIAPHRAGM	PLEURAL THICKENING: COSTOPHRENIC ANGLE OBLITERATION	PLEURAL CALCIFICATION	SYMBOLS	COMMENTS
3/3; s/s	2	3/3	s/s	R L ✓✓ / ✓✓ / ✓✓	No	No	Yes R L ✓✓ Width: a a Extent: 3 3	No	No	No	ho; ih; pi.	Quality defect: radiograph is too light. Honeycomb lung appearance is not marked.
1/1; t/t Costophrenic angle obliteration	1	1/1	t/t	R L _ _ / ✓✓ / ✓✓	No	No	Yes R L ✓✓ Width: a a Extent: 2 2	No	Yes R L ✓ _	Yes R L _ ✓ Extent: 2	None	This radiograph defines the lower limit for costophrenic angle obliteration. Note shrinkage in lower lung fields.
2/2; t/t	1	2/2	t/t	R L ✓✓ / ✓✓ / ✓✓	No	No	Yes R L ✓✓ Width: a a Extent: 1 1	No	No	No	ih.	Pleural thickening is present in the apices of the lung.
3/3; t/t	1	3/3	t/t	R L ✓✓ / ✓✓ / ✓✓	No	No	No	No	No	No	hi; ho; id; ih; tb.	None
1/1; u/u 2/2; u/u 3/3; u/u	-	-	-	-	-	-	-	-	-	-	-	This composite radiograph illustrates the mid-categories of profusion of small opacities classifiable for shape and size as u/u.
A	2	2/2	p/q	R L ✓✓ / ✓✓ / ✓✓	A	No	No	No	No	No	None	Quality defects: radiograph is too light and pleural definition is poor.

DESCRIPTIONS OF STANDARD RADIOGRAPHS (continued)

1980 STANDARD RADIOGRAPHS SHOWING	TECHNICAL QUALITY	SMALL OPACITIES: PROFUSION	SMALL OPACITIES: SHAPE-SIZE	SMALL OPACITIES: EXTENT	LARGE OPACITIES	PLEURAL THICKENING: CHEST WALL: CIRCUM-SCRIBED (PLAQUES)	PLEURAL THICKENING: CHEST WALL: DIFFUSE	PLEURAL THICKENING: DIAPHRAGM	PLEURAL THICKENING: COSTOPHRENIC ANGLE OBLITERATION	PLEURAL CALCIFICATION	SYMBOLS	COMMENTS
B	1	1/2	p/q	R L ✓ ✓ ✓ ✓ ✓ ✓	B	No	No	No	No	No	ax; co.	Definition of pleura is slightly imperfect.
C	1	2/1	q/t	R L ✓ ✓ ✓ ✓ ✓ ✓	C	No	No	No	No	No	bu; di; em; es; hi; ih.	The small opacities are difficult to classify because of the presence of the large opacities. Note the left costophrenic angle obliteration. This is not classifiable because it does not reach the lower limit defined by the standard radiograph 1/1; t/t.
Pleural thickening (circum-scribed)	-	-	-	-	-	Yes	No	No	No	No	-	The pleural thickening present face on, is of indeterminate width, and extent 2.
Pleural thickening (diffuse)	-	-	-	-	-	No	Yes	No	No	Yes	-	The pleural thickening present in profile, is of width e, and extent 2. Not associated small calcifications.
Pleural thickening (calcifi-cation) diaphragm	-	-	-	-	-	No	No	Yes	No	Yes	-	Circumscribed, calcified pleural thickening of extent 2.
Pleural thickening (calcifi-cation) chest wall	-	-	-	-	-	Yes	No	No	No	Yes	-	Calcified and uncalcified pleural thickening present face on, is of indeterminate width, and extent 2.

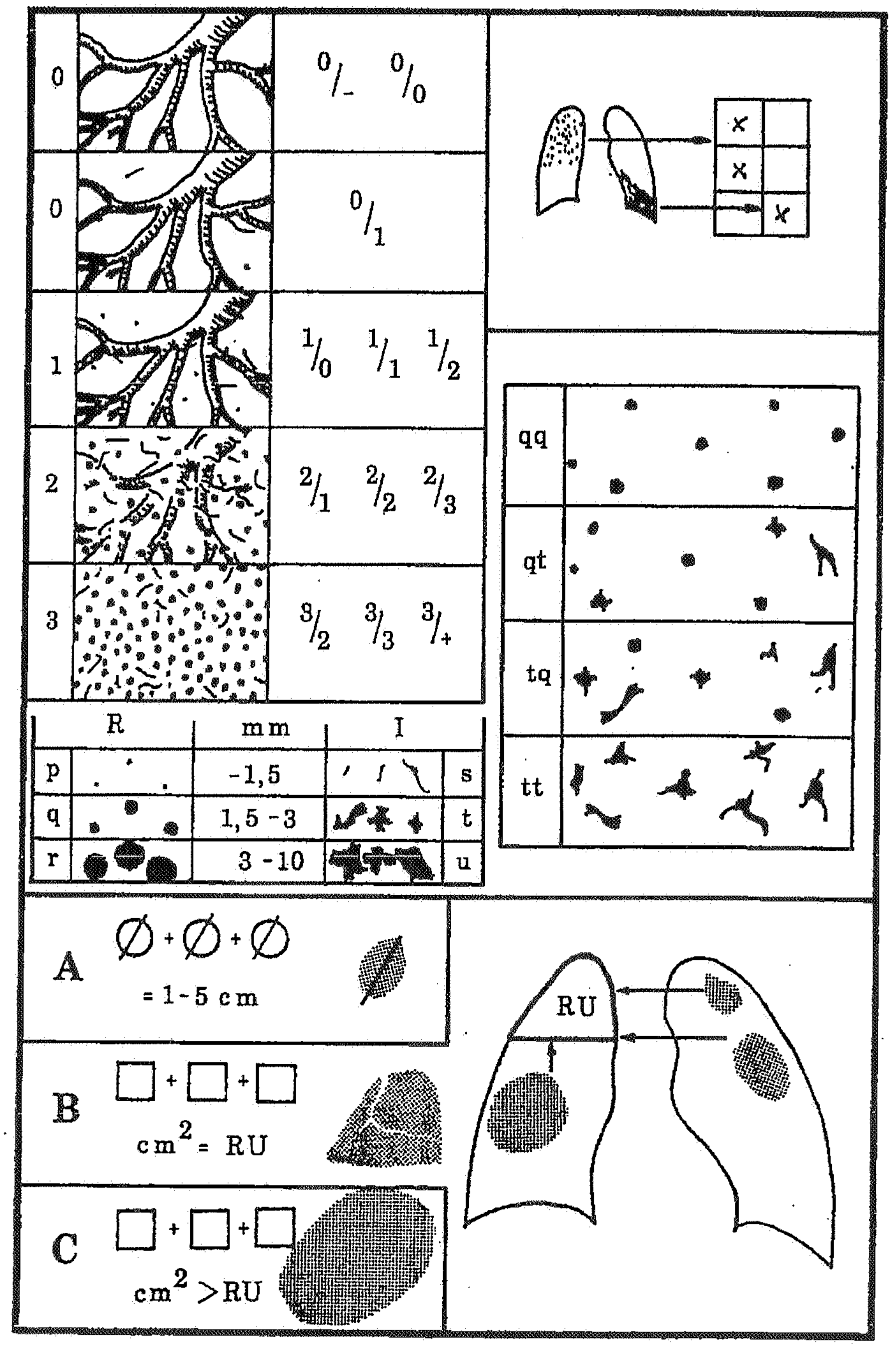
APPENDIX F

DIAGRAMS*

The diagrams on the following pages are intended only to provide a pictorial aide memoire to the definitions of the Complete Classification and they do not subsitute for the standard radiographs or the written text.

The diagrams representing the symbols provide simple reminders of the symbols to be used, particularly for those whose main language is not English. It is recognised that these diagrams can not possibly illustrate all the manifestations of many of the symbols, for example ca, cp, od.

* Prepared by H. Bohlig and R. Kiviluoto.



0
$^0/_-$ $^0/_0$
0
$^0/_1$
1
$^1/_0$ $^1/_1$ $^1/_2$
2
$^2/_1$ $^2/_2$ $^2/_3$
3
$^3/_2$ $^3/_3$ $^3/_+$
R
mm
I
p
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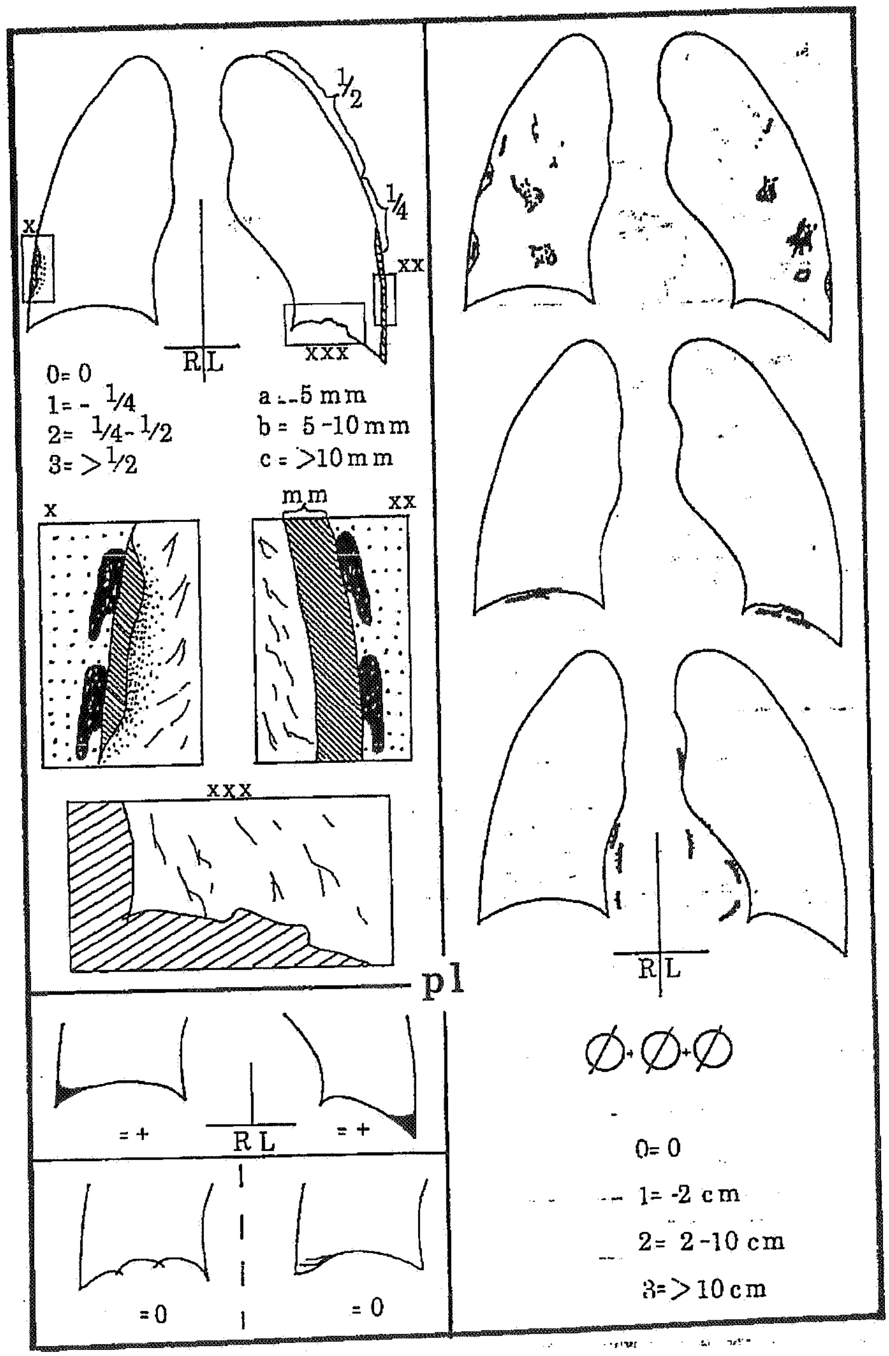
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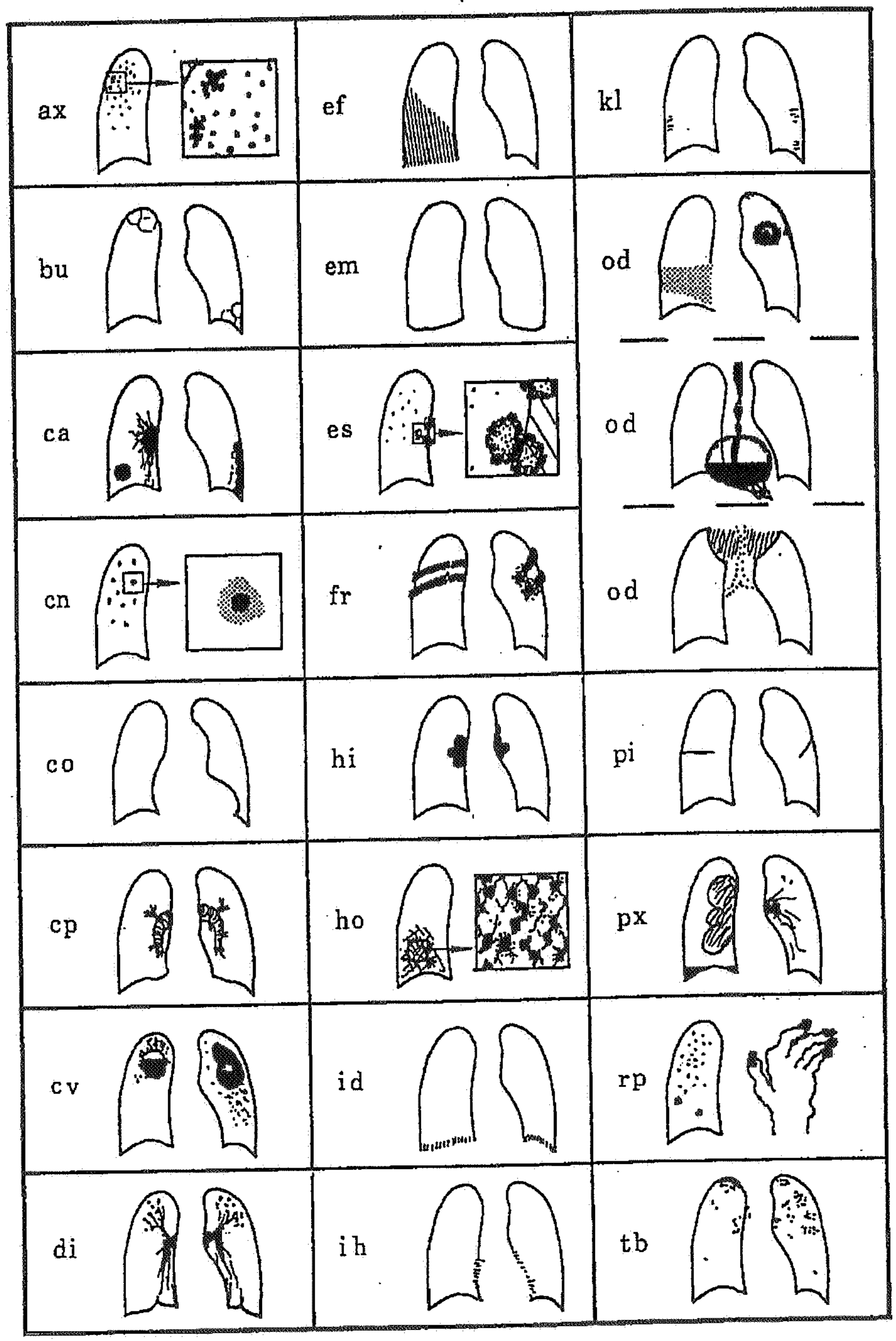
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APPENDIX G

ILO 1980 INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF THE PNEUMOCONIOSES

SUMMARY OF DETAILS OF CLASSIFICATION

FEATURES		CODES	DEFINITIONS
TECHNICAL QUALITY		1 2 3 4	Good. Acceptable, with no technical defect likely to impair classification of the radiograph for pneumoconiosis. Poor, with some technical defect but still acceptable for classification purposes. Unacceptable.
PARENCHYMAL ABNORMALITIES Small opacities	Profusion		The category of profusion is based on assessment of the concentration of opacities by comparison with the standard radiographs.
		0/- 0/0 0/1 1/0 1/1 1/2 2/1 2/2 2/3 3/2 3/3 3/+	Category 0 – small opacities absent or less profuse than the lower limit of category 1. Categories 1, 2 and 3 – represent increasing profusion of small opacities as defined by the corresponding standard radiographs.
	Extent	RU RM RL LU LM LL	The zones in which the opacities are seen are recorded. The right (R) and left (L) thorax are both divided into three zones – upper (U), middle (M) and lower (L). The category of profusion is determined by considering the profusion as a whole over the affected zones of the lung and by comparing this with the standard radiographs.
	Shape and Size rounded	p/p q/q r/r	The letters p, q and r denote the presence of small rounded opacities. Three sizes are defined by the appearances on standard radiographs. p = diameter up to about 1.5mm. q = diameter exceeding about 1.5mm and up to about 3mm. r = diameter exceeding about 3mm and up to about 10mm.
	irregular	s/s t/t u/u	The letters s, t and u denote the presence of small irregular opacities. Three sizes are defined by the appearances on standard radiographs. s = width up to about to 1.5mm. t = width exceeding about 1.5mm and up to about 3mm. u = width exceeding 3mm and up to about 10mm.
	mixed	p/s p/t p/u p/q p/r q/s q/t q/u q/p q/r r/s r/t r/u r/p r/q s/p s/q s/r s/t s/u t/p t/q t/r t/s t/u u/p u/q u/r u/s u/t	For mixed shapes (or sizes) of small opacities the predominant shape and size is recorded first. The presence of a significant number of another shape and size is recorded after the oblique stroke.

FEATURES		CODES	DEFINITIONS
Large opacities		A B C	The categories are defined in terms of the dimensions of the opacities. Category A – an opacity having a greatest diameter exceeding about 10mm and up to and including 50mm, or several opacities each greater than about 10mm, the sum of whose greatest diameters does not exceed about 50mm. Category B – one or more opacities larger or more numerous than those in category A whose combined area does not exceed the equivalent of the right upper zone. Category C – one or more opacities whose combined area exceeds the equivalent of the right upper zone.
PLEURAL ABNORMALITIES Pleural Thickening			
Chest wall	Type		Two types of pleural thickening of the chest wall are recognised: circumscribed (plaques) and diffuse. Both types may occur together.
	Site	R L	Pleural thickening of the chest wall is recorded separately for the right (R) and left (L) thorax.
	Width	a b c	For pleural thickening seen along the lateral chest wall the measurement of maximum width is made from the inner line of the chest wall to the inner margin of the shadow seen most sharply at the parenchymal-pleural boundary. The maximum width usually occurs at the inner margin of the rib shadow at its outermost point. a = maximum width up to about 5mm. b = maximum width over about 5mm and up to about 10mm. c = maximum width over about 10mm.
	Face on	Y N	The presence of pleural thickening seen face-on is recorded even if it can be seen also in profile. If pleural thickening is seen face-on only, width can not usually be measured.
	Extent	1 2 3	Extent of pleural thickening is defined in terms of the maximum length of pleural involvement, or as the sum of maximum lengths, whether seen in profile or face-on. 1 = total length equivalent up to one quarter of the projection of the lateral chest wall. 2 = total length exceeding one quarter but not one half of the projection of the lateral chest wall. 3 = total length exceeding one half of the projection of the lateral chest wall.
Diaphragm	Presence	Y N	A plaque involving the diaphragmatic pleura is recorded as present (Y) or absent (N), separately for the right (R) and left (L) thorax.
	Site	R L	

FEATURES		CODES	DEFINITIONS
Costophrenic angle obliteration	Presence	Y N	The presence (Y) or absence (N) of costophrenic angle obliteration is recorded separately from thickening over other areas, for the right (R) and left (L). thorax. The lower limit for this obliteration is defined by a standard radiograph.
	Site	R L	If the thickening extends up the chest wall then both costophrenic angle obliteration and pleural thickening should be recorded.
Pleural calcification			The site and extent of pleural calcification are recorded separately for the two lungs, and the extent defined in terms of dimensions.
	Site		
	chest wall	R L	
	diaphragm	R L	
	other	R L	"other" includes calcification of the mediastinal and pericardial pleura.
	Extent	1 2 3	1 = an area of calcified pleura with greatest diameter up to about 20mm, or a number of such areas the sum of whose greatest diameters does not exceed about 20mm. 2 = an area of calcified pleura with greatest diameter exceeding about 20mm and up to about 100mm, or a number of such areas the sum of whose greatest diameters exceeds about 20mm but does not exceed about 100mm. 3 = an area of calcified pleura with greatest diameter exceeding about 100mm, or a number of such areas whose sum of greatest diameters exceeds about 100mm.
SYMBOLS			It is to be taken that the definition of each of the Symbols is preceded by an appropriate word or phrase such as "suspect", "changes suggestive of", or "opacities suggestive of", etc.
		ax	- coalescence of small pneumoconiotic opacities
		bu	- bulla(e)
		ca	- cancer of lung or pleura
		cn	- calcification in small pneumoconiotic opacities
		co	- abnormality of cardiac size or shape
		cp	- cor pulmonale
		cv	- cavity
		di	- marked distortion of the intrathoracic organs
		ef	- effusion
		em	- definite emphysema
		es	- eggshell calcification of hilar or mediastinal lymph nodes
		fr	- fractured rib(s)
		hi	- enlargement of hilar or mediastinal lymph nodes
		ho	- honeycomb lung
		id	- ill-defined diaphragm
		ih	- ill-defined heart outline
		kl	- septal (Kerley) lines
		od	- other significant abnormality
		pi	- pleural thickening in the interlobar fissure or mediastinum
		px	- pneumothorax
		rp	- rheumatoid pneumoconiosis
		tb	- tuberculosis
COMMENTS	Presence	Y N	Comments should be recorded pertaining to the classification of the radiograph, particularly if some other cause is thought to be responsible for a shadow which could be thought by others to have been due to pneumoconiosis; also to identify radiographs for which the technical quality may have affected the reading materially.

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Guidelines for the use of the ILO International Classification of Radiographs of Pneumoconioses

OCCUPATIONAL SAFETY AND HEALTH SERIES No. 22 (Rev. 2000)

GUIDELINES FOR THE USE OF THE ILO INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF PNEUMOCONIOSES

Revised edition 2000

INTERNATIONAL LABOUR OFFICE · GENEVA

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Foreword

Over the last seven decades the International Labour Office (ILO) has promoted discussion and published a series of guidelines on how to classify chest radiographs of persons with pneumoconioses. The goals have been to standardize classification methods and facilitate international comparisons of data on pneumoconioses, epidemiological investigations and research reports. This revised edition of the ILO's International Classification of Radiographs of Pneumoconioses is a further effort towards these objectives. Based on the principles that governed the development of earlier editions of the Classification (those of 1950, 1958, 1968, 1971 and 1980), it refers to radiological appearances seen in all types of pneumoconioses. The description of the scheme in this revision of the *Guidelines* is more concise than previously. Some ambiguities in earlier editions have been clarified further, and the conventions for classifying pleural abnormalities have been revised. The changes are based on a comprehensive review of experience in using the preceding (1980) edition of the Classification.

The ILO initiated the review process in November 1989 at a meeting of 11 experts from seven countries. Participants were asked to advise on the kind of changes to the scheme that might be desirable, and to reconsider the suitability of the standard radiographs that accompanied the 1980 edition. Some parts of the *Guidelines* were identified as requiring revision, but the importance of continuity in the Classification was re-emphasized. With this in mind, it was agreed that the set of standard radiographs that were distributed with the 1980 edition should be retained, although it was recognized that the technical quality of many of them was inferior to that available with modern equipment and techniques. Participants in the meeting also suggested that the number of radiographs included in the complete set of standards (22) might be usefully reduced by reproducing critical parts from some of them onto quadrant sections of full-size radiographs. It was agreed, however, that it was necessary to verify that such a reform would not, in itself, result in a change in the way that radiographs of persons exposed to dust were classified. A controlled trial was therefore arranged by the ILO and the Division of Respiratory Disease Studies of the United States National Institute for Occupational Safety and Health (NIOSH). This involved 40 physicians, working at specialized clinical and research centres in ten countries (see Appendix F).

Results from the trial showed that the proposed modification to the ILO standard radiographs, involving reproduction of sections from 15 of the ILO (1980) standards onto five new "quadrant" radiographs, would not increase variability between readers, and might improve the reproducibility of small-opacity profusion classification in some respects, but could also reduce slightly the frequency with which some readers identify large opacities. Use of the standards containing the quadrant radiographs was associated with an increase in the frequency with which some readers described the shapes of the small opacities that they saw as predominantly irregular, rather than rounded. It was concluded, however, that the effects found were unlikely to be distinguishable from inter- and intra-reader variability in most occupational health survey situations.[1]

In October 1997 more than 200 participants in the Ninth International Conference on Occupational Respiratory Diseases in Kyoto, Japan, attended an ILO-convened Working Group on the Classification. That meeting recommended further work on the development of quadrant or sectional composite radiographs and improved techniques for standard radiograph reproduction prior to the introduction of revised standard radiographs. A smaller group of experts attending the same conference then considered in detail a draft revised text of the *Guidelines* to the Classification. Discussion of this draft continued at a further meeting in March 1998 at the offices of the American College of Radiology (ACR) in Reston, Virginia, and was concluded on 26 October 2000 at the ILO Branch Office in Washington, DC. Participants in the latter meeting also compared two types of new copies of several sets of ILO (1980) standard radiographs, of sectional quadrant radiographs that had been used in the international trial, and of a newly prepared composite radiograph illustrating pleural abnormalities. The new copies that were under review were produced from earlier copies, both by standard film copying methods and by improved techniques from digitized versions of the earlier copies. The experts preferred the copies made from the digitized versions, and they recommended the use of this technology and the associated reproduction process for producing future copies of ILO standard radiographs. The individuals who attended the various ILO-convened meetings concerned with the revision of the Classification are listed in Appendix F.

The ILO (2000) International Classification of Radiographs of Pneumoconioses is accompanied by two sets of standard radiographs, as described in Appendix C. Both sets are available from the ILO. The first ("Complete") Set consists of 22 radiographs. Twenty of them are new copies from digitized full-size standard radiographs distributed previously with the 1980 edition of the ILO Classification. A further radiograph illustrates u/u-sized irregular opacities. Three quadrants of this radiograph reproduce the sections of the composite radiograph that was used in 1980 to depict increasing profusion of u/u-sized irregular opacities; the fourth quadrant illustrates subcategory 0/0. A new composite radiograph is provided to illustrate pleural abnormalities.

The "Quad" Set consists of 14 radiographs. Nine of them are the most commonly used standards from the Complete Set. The other five reproduce (quadrant) sections of the remaining radiographs in the Complete Set.

The development of this revised (2000) edition of the *Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses* has been made possible by virtue of intensive and sustained activity on the part of many individuals and organizations. Some of them are named in Appendix F. Others, too numerous to list, provided valuable comments and suggestions in writing and by contributing to discussions at various scientific meetings, including four ILO international conferences on pneumoconioses and occupational lung diseases (Bochum, Germany, 1983; Pittsburgh, Pennsylvania, 1987; Prague, 1992; and Kyoto, 1997). The ILO wishes to express its sincere thanks to all concerned, and to acknowledge gratefully the active assistance from the Committee on Pneumoconiosis (previously the Task Force on Pneumoconiosis) of the American College of Radiology (ACR), the United States National Institute for Occupational Safety and Health (NIOSH), the Rosai Hospital for Silicosis in Japan, the WHO Collaborating

[1] *A trial of additional composite standard radiographs for use with the ILO International Classification of Radiographs of Pneumoconioses*, NIOSH Report No. HETA 93-0340, July 1997, available from National Technical Information Service (NTIS), 5825 Port Royal Road, Springfield, Virginia 2216, United States. A shorter report has been published: "New composite ("Quadrant") standard films for classifying radiographs of pneumoconioses", in *Industrial Health*, Vol. 36, No. 4, Oct. 1998, pp. 380-383.

Centre for Radiological Education in Sweden, the Finnish Institute of Occupational Health, the German Committee for Diagnostic Radiology of Occupational and Environmental Diseases, and the Institute for Occupational and Social Medicine of the University of Cologne. Continuing use of the ILO International Classification of Radiographs of Pneumoconioses will contribute further to the protection of the health of workers in dusty occupations.

1

Introduction

Scope of the Classification

The Classification provides a means for describing and recording systematically the radiographic abnormalities in the chest provoked by the inhalation of dusts. It is used to describe radiographic abnormalities that occur in any type of pneumoconiosis and is designed for classifying only the appearances seen on postero-anterior chest radiographs. Other views and imaging techniques may be required for clinical assessment of individuals, but the ILO International Classification has not been designed to code such findings.

Object of the Classification

The object of the Classification is to codify the radiographic abnormalities of the pneumoconioses in a simple, reproducible manner. The Classification neither defines pathological entities nor takes into account working capacity. It does not imply legal definitions of pneumoconioses for compensation purposes and does not set or imply a level at which compensation is payable.

Uses of the Classification

The Classification is used internationally for epidemiological research, for screening and surveillance of those in dusty occupations, and for clinical purposes. Use of the scheme may lead to better international comparability of data concerning the pneumoconioses.

Standard radiographs and written definitions

The Classification consists of a set of standard radiographs and this text, with the accompanying footnotes. These footnotes are intended to reduce ambiguity and are based on experience with earlier editions of the ILO Classification. In some parts of the scheme, the standard radiographs take precedence over the written definitions. The text makes it clear when this is so.

2

General instructions

No radiographic features are pathognomonic of dust exposure. Some radiographic features that are unrelated to inhaled dust may mimic those caused by dust. Readers may differ about the interpretation of such appearances.

In epidemiological studies, therefore, the study protocol will usually require that all appearances described in these *Guidelines* and seen on the standard radiographs are to be classified. Symbols must always be used and appropriate Comments must be reported.[1]

When the Classification is used for some clinical purposes, the protocol may require that medical readers classify only those appearances which the reader believes or suspects to be pneumoconiotic in origin. Symbols must always be used and appropriate Comments must be reported.[1]

[1] See sections 3.4 and 3.5

3

Specific instructions for use of the Complete Classification

3.1. Technical quality[2,3]

Four grades of technical quality are used:

1. Good.
2. Acceptable, with no technical defect likely to impair classification of the radiograph for pneumoconiosis.
3. Acceptable, with some technical defect but still adequate for classification purposes.
4. Unacceptable for classification purposes.

If technical quality is not grade 1, a Comment must be made about the technical defects.

3.2. Parenchymal abnormalities

Parenchymal abnormalities include both small opacities and large opacities.

Small opacities

Small opacities are described by *profusion, affected zones of the lung, shape (rounded or irregular)* and *size*. The order of identifying and recording the presence or absence of these findings while classifying a radiograph is left to the reader's preference.

Profusion

The *profusion* of small opacities refers to the concentration of small opacities in affected zones of the lung. The category of profusion is based on comparisons with the standard radiographs. For profusion the written descriptions are a guide, but the standard

[2] Appendix A emphasizes the importance of good radiographic quality for the interpretation of chest radiographs. It is essential to produce radiographs that show clearly both the parenchyma and the pleural characteristics. For clinical purposes, special views or techniques may also be required. When it is not possible to replace a grade 3 radiograph by a better one, more details about technical defects should be recorded.

[3] The standard radiographs are not to be considered in determining technical quality of the subject radiographs. The standard radiographs were chosen to demonstrate the radiographic features of the pneumoconioses, rather than to demonstrate technical quality.

radiographs take precedence. Four categories are defined by the standard radiographs. Profusion is classified into one of 12 ordered subcategories, which are represented symbolically as follows.[4]

Increasing profusion of small opacities ⟶

Categories	**0**			**1**			**2**			**3**		
Subcategories	0/–	0/0	0/1	1/0	1/1	1/2	2/1	2/2	2/3	3/2	3/3	3/+

Category **0** refers to the absence of small opacities or the presence of small opacities that are less profuse than category **1**.

Classification of a radiograph using the 12-subcategory scale is performed as follows. The appropriate category is chosen by comparing a subject radiograph with standard radiographs that define the levels of profusion characteristic of the centrally placed subcategories (**0/0**, **1/1**, **2/2**, **3/3**) within these categories. The category is recorded by writing the corresponding symbol followed by an oblique stroke, i.e. **0/** , **1/** , **2/** , **3/**. If no alternative category was seriously considered, the radiograph is classified into the central subcategory, i.e. **0/0**, **1/1**, **2/2**, **3/3**. For example, a radiograph that shows profusion which is considered to be similar to that shown on a subcategory **2/2** standard radiograph, i.e. neither category **1** nor **3** was seriously considered as an alternative, would be classified as **2/2**. However, subcategory **2/1** refers to a radiograph with profusion of small opacities judged to be similar in appearance to that depicted on a subcategory **2/2** standard radiograph, but category **1** was seriously considered as an alternative before deciding to classify it as category **2**.

The standard radiographs provide examples of appearances classifiable as subcategory **0/0**. Subcategory **0/0** refers to radiographs where there are no small opacities, or if a few are thought to be present, they are not sufficiently definite or numerous for category **1** to have been seriously considered as an alternative. Subcategory **0/1** is used for radiographs classified as category **0** after having seriously considered category **1** as an alternative. Subcategory **1/0** is used for radiographs classified as category **1** after having seriously considered category **0** as an alternative. If the absence of small opacities is particularly obvious, then the radiograph is classified as subcategory **0/–**.

A radiograph showing profusion much greater than that depicted on a subcategory **3/3** standard radiograph is classified as subcategory **3/+**.

[4] The 12 subcategories refer only to the profusion of small opacities. Profusion, including references to subcategories 0/– or 0/0 when appropriate, must always be recorded, irrespective of any other abnormalities that may be present. Conversely, when other abnormalities are seen, their presence must also be recorded, irrespective of whether any small opacities are present. The subcategories are arbitrary divisions of an underlying continuum of increasing profusion of small opacities. Those divisions are defined by the standard radiographs, together with the instructions for their use. The validity of the classification procedure to represent this continuum has been demonstrated in studies of relationships between results obtained by using the ILO Classification and (a) indices of cumulative exposures to various dusts; (b) the dust content of coalminers' lungs post mortem; (c) mortality of asbestos workers and coalminers; and (d) pathological appearances of coalminers' lungs post

Affected zones

The zones in which the opacities are seen are recorded. Each lung field is divided into three zones (upper, middle, lower) by horizontal lines drawn at approximately one-third and two-thirds of the vertical distance between the lung apices and the domes of the diaphragm.

The overall profusion of small opacities is determined by considering the profusion as a whole over *affected zones* of the lungs. When there is a marked (three subcategories or more) difference in profusion in different zones of the lungs, then the zone or zones showing the marked lesser degree of profusion is/are ignored for the purpose of classifying the overall profusion.[5]

Shape and size

For shape and size, the written definitions are a guide, and the standard radiographs take precedence. The shape and size of small opacities are recorded. Two kinds of shape are recognized: rounded and irregular. In each case, three sizes are differentiated.

For small rounded opacities, the three size ranges are denoted by the letters **p, q** and **r**, and are defined by the appearances of the small opacities on the corresponding standard radiographs. These illustrate:

p-opacities with diameters up to about 1.5 mm;
q-opacities with diameters exceeding about 1.5 mm and up to about 3 mm;
r-opacities with diameters exceeding about 3 mm and up to about 10 mm.

The three size ranges of small irregular opacities are denoted by the letters **s, t** and **u**, and are defined by the appearances of the small opacities on the corresponding standard radiographs. These illustrate:

s-opacities with widths up to about 1.5 mm;
t-opacities with widths exceeding about 1.5 mm and up to about 3 mm;
u-opacities with widths exceeding about 3 mm and up to about 10 mm.

[5] A "marked (three subcategories or more) difference" in profusion in different zones of the lung is present when there are two or more subcategories of profusion *between* the zone (or zones) of the lowest profusion *and* the zone (or zones) of the highest profusion. For example, if a subject radiograph displays zones with profusion levels 1/1, 1/2, 2/1 and 2/2, the overall profusion is determined by ignoring the zone with profusion level 1/1, since two or more subcategories (1/2, 2/1) are between that zone and the zone of the highest profusion (2/2). The overall profusion, therefore, is determined by considering only the affected zones showing profusion levels 1/2, 2/1 and 2/2, since there is only one subcategory of profusion (2/1) between profusion levels 1/2 and 2/2.

Example 1

Only one intervening subcategory between the zones of lowest (1/2) and highest (2/2) profusion; use all three to determine overall profusion.

1/1 1/2 2/1 2/2

There are two intervening subcategories between the zones of lowest (1/1) and highest (2/2) profusion; ignore 1/1 to determine overall profusion.

Example 2

Only one intervening subcategory between the zones of lowest (2/1) and highest (2/3) profusion; use all three to determine overall profusion.

1/1 1/2 2/1 2/2 2/3

There are three intervening subcategories between the zones of lowest (1/1) and highest (2/3) profusion; ignore 1/1 and 1/2; use 2/1, 2/2, 2/3 to determine overall profusion since there is only one subcategory between 2/1 and 2/3.

All zones in which opacities are seen *are recorded*, irrespective of whether some are later ignored in determining overall profusion.

Two letters must be used to record shape and size. Thus, if the reader considers that all, or virtually all, opacities seen are of one shape and size, then this is noted by recording the letter twice, separated by an oblique stroke (for example **q/q**). If, however, significant numbers of another shape or size are seen, then this is recorded by writing a different letter after the oblique stroke (for example **q/t**); **q/t** would mean that the predominant small opacities are rounded and of size **q**, but that there are significant numbers of small irregular opacities present of size **t**. In this way, any combination of small opacities may be recorded.[6] When small opacities of different shapes and/or size are seen, the letter for the predominant shape and size (primary) is recorded before the oblique stroke, while the letter for the less frequently occurring shape and size (secondary) is recorded after the oblique stroke.

Large opacities

A large opacity is defined as an opacity having the longest dimension exceeding 10 mm. Categories of large opacities are defined below. These definitions take precedence over the examples of large opacities illustrated on standard radiographs.

Category **A** One large opacity having the longest dimension up to about 50 mm, or several large opacities with the sum of their longest dimensions not exceeding about 50 mm.

Category **B** One large opacity having the longest dimension exceeding 50 mm but not exceeding the equivalent area of the right upper zone, or several large opacities with the sum of their longest dimensions exceeding 50 mm but not exceeding the equivalent area of the right upper zone.

Category **C** One large opacity which exceeds the equivalent area of the right upper zone, or several large opacities which, when combined, exceed the equivalent area of the right upper zone.

3.3. Pleural abnormalities

Pleural abnormalities are divided into pleural plaques (localized pleural thickening), costophrenic angle obliteration and diffuse pleural thickening.

Pleural plaques (localized pleural thickening)

Pleural plaques represent localized pleural thickening, generally of the parietal pleura. Pleural plaques may be seen on the diaphragm, on the chest wall (in-profile or face-on), and at other sites. At times, they are recognized only by their calcification. Pleural plaques are recorded as absent or present. If present on the chest wall, they are recorded as in-profile or face-on, and separately for the right and left sides. A minimum width of about 3 mm is required for an in-profile plaque to be recorded as present.[7,8]

[6] See Appendix E for possible combinations.

[7] The measurement of width is made from the innermost margin of the rib to the innermost sharp margin of the plaque at the pleural-parenchymal boundary.

[8] If more detailed measurement of width is required for a particular study, three categories may be used:
a – about 3 mm up to about 5 mm;
b – about 5 mm up to about 10 mm;

Site, calcification and extent of pleural plaques are recorded separately for the right and for the left side of the chest. The written guidelines describing these features take precedence over the examples provided on the standard radiograph.

Site

The sites (locations) of pleural plaques include chest wall, diaphragm and other sites. Other sites include the mediastinal pleura in the para-spinal or para-cardiac locations. The presence or absence of pleural plaques is recorded for all sites, and separately for the right and for the left sides.

Calcification

Radiographic images of pleural plaques may include recognizable areas of calcification. The presence or absence of calcification is recorded for all plaques, and separately for the right and for the left sides. When calcification is seen, a plaque is also recorded as present at that site.

Extent

Extent is not recorded for plaques on the diaphragm or at other sites. It is recorded only for plaques along the chest wall, and is combined for both in-profile and face-on varieties. Extent is defined in terms of the total length of involvement with respect to the projection of the lateral chest wall (from the apex to the costophrenic angle) on the postero–anterior chest radiograph:

1 = total length up to one-quarter of the projection of the lateral chest wall;

2 = total length exceeding one-quarter and up to one-half of the projection of the lateral chest wall;

3 = total length exceeding one-half of the projection of the lateral chest wall.

Costophrenic angle obliteration

Costophrenic angle obliteration is recorded as either present or absent, separately for the right and for the left side. The lower limit for recording costophrenic angle obliteration is defined by the standard radiograph showing profusion subcategory **1/1 t/t**. If the pleural thickening extends up the lateral chest wall from the obliterated costophrenic angle, the thickening should be classified as diffuse pleural thickening. Costophrenic angle obliteration may occur without diffuse pleural thickening.

Diffuse pleural thickening

Diffuse pleural thickening historically has referred to thickening of the visceral pleura. The radiological distinction between parietal and visceral pleural thickening is not always possible on a postero–anterior radiograph.

For the purpose of the ILO (2000) Classification, diffuse pleural thickening extending up the lateral chest wall is recorded *only* in the presence of, and in continuity with, an obliterated costophrenic angle. Diffuse pleural thickening is recorded as absent or present along the chest wall. If present, it is recorded as in-profile or face-on, and separately for the right and the left side. Its extent is recorded in the same manner as for pleural plaques. A minimum width of about 3 mm is required for in-profile diffuse pleural thickening to be recorded as present. If detailed measurement of its width is required for a particular study, see the comment provided in footnote 8.

Calcification and extent of diffuse pleural thickening on the chest wall are recorded separately for the right and for the left side (see guidelines for pleural plaques). The pleura may often be seen at the apex of the lung and should not be recorded as part of diffuse pleural thickening of the chest wall.

3.4. Symbols

Symbols to record radiographic features of importance are listed below. Their use is relevant because they describe additional features related to dust exposure and other aetiologies. Use of these symbols is obligatory.[9]

Some of the symbols imply interpretations, rather than just descriptions, of what is seen on the radiograph. A postero–anterior chest radiograph on its own may not be sufficient to justify definitive interpretation; therefore, each of the following definitions of symbols assumes an introductory qualifying word or phrase such as "changes indicative of", or "opacities suggestive of", or "suspect".

The symbols are:

aa atherosclerotic aorta
at significant apical pleural thickening (see Appendix D)
ax coalescence of small opacities[10]
bu bulla(e)
ca cancer: thoracic malignancies excluding mesothelioma
cg calcified non-pneumoconiotic nodules (e.g. granuloma) or nodes
cn calcification in small pneumoconiotic opacities
co abnormality of cardiac size or shape
cp cor pulmonale
cv cavity
di marked distortion of an intrathoracic structure
ef pleural effusion
em emphysema
es eggshell calcification of hilar or mediastinal lymph nodes
fr fractured rib(s) (acute or healed)
hi enlargement of non-calcified hilar or mediastinal lymph nodes
ho honeycomb lung
id ill-defined diaphragm border[11]
ih ill-defined heart border[12]
kl septal (Kerley) lines
me mesothelioma

[9] Inclusion of this information in statistical analyses of results may help to explain otherwise inexplicable variation between readers in their classifications of the same radiographs.

[10] The symbol **ax** represents coalescence of small opacities with margins of the small opacities remaining visible, whereas a large opacity demonstrates a homogeneous opaque appearance. The symbol **ax** (coalescence of small opacities) may be recorded either in the presence or in the absence of large opacities.

[11] The symbol **id** (ill-defined diaphragm border) should be recorded only if more than one-third of one hemidiaphragm is affected.

[12] The symbol **ih** (ill-defined heart border) should be recorded only if the length of the heart border

pa plate atelectasis
pb parenchymal bands[13]
pi pleural thickening of an interlobar fissure[14]
px pneumothorax
ra rounded atelectasis
rp rheumatoid pneumoconiosis[15]
tb tuberculosis[16]
od other disease or significant abnormality[17]

3.5. Comments

If the technical quality of the radiograph is not recorded as 1 (good), then a Comment on why this is so should be made at that time, before proceeding with the classification.

Comments are also required if the symbol **od** (other disease) is recorded, and to identify any part of the reading of a chest radiograph which is believed by a reader to be probably or certainly not dust related.

Comments should also be recorded to provide other relevant information.

[13] Significant parenchymal fibrotic strands in continuity with the pleura.

[14] Illustrated on the 3/3 s/s standard radiograph.

[15] Illustrated on the 1/1 p/p standard radiograph.

[16] The symbol tb should be used for either suspect active or suspect inactive tuberculosis. The symbol tb should not be used for the calcified granuloma of tuberculosis or other granulomatous processes, e.g. histoplasmosis. Such appearances should be recorded as cg.

4

Specific instructions for the use of the Abbreviated Classification

The Abbreviated Classification, described below, is a simplified version of the Complete Classification and includes its major components.

Technical quality

The recording of the technical quality of the radiograph is the same as for the Complete Classification (see section 3.1).

Small opacities

Profusion is determined by comparison with standard radiographs and recorded as one of the categories: **0**, **1**, **2** or **3** (see section 3.2).

Shape and size are determined by comparison with standard radiographs. The predominant shape and size are recorded using only one of the following letters: **p**, **q**, **r**, **s**, **t** or **u** (see section 3.2).

Large opacities

Large opacities are recorded as size **A**, **B** or **C**, in the same way as for the Complete Classification (see section 3.2).

Pleural abnormalities

All types of pleural thickening are recorded by the letters **PT**.
All types of pleural calcifications are recorded by the letters **PC**.

Symbols

Symbols are recorded as for the Complete Classification (see section 3.4).

Comments

Comments are recorded as for the Complete Classification (see section 3.5).

5

Using the ILO Classification

Efficient use of the ILO Classification requires good viewing and recording conditions. The following recommendations are particularly important for epidemiological studies.

Viewing

The illuminated boxes for viewing the radiographs to be classified and the standard radiographs must be close enough for the observer to see opacities only 1 mm in diameter, that is, a distance of about 250 mm. It is also essential to view the entire radiograph. The observer should be seated comfortably.

The minimum number of viewing spaces is two, allowing comparisons between the subject radiograph and the standard radiographs. However, it is recommended that three viewing spaces be used, so that the subject radiograph can be placed between the appropriate standard radiographs to assess profusion. It is important to make it easy to select and put up the standard radiographs for comparison, which is mandatory.

The viewing surfaces must be clean and the intensity of illumination should be uniform over all surfaces. The general illumination in the room should be low, without direct daylight. The room should be quiet, comfortable and free from distractions.

Epidemiological reading protocols

When classifying radiographs for epidemiological purposes, it is essential that the reader does not consider any other information about the individuals being studied. Awareness of supplementary details specific to individuals can introduce bias into results. If the epidemiological objective is to make comparisons between two or more groups, then the radiographs from all groups should be mixed and presented to the reader in random order. Failure to observe these principles may invalidate conclusions from the study.

Recording

Recording of results should be standardized and systematic. It is important to make provision for recording explicitly the presence or absence of all features to be evaluated for a particular study. Clerical help for recording results is valuable when classifying large numbers of radiographs. The clerical assistant should be asked to remind the reader of failure to report the presence or absence of any features to be analysed in the study.

Reading rates

The number of radiographs classifiable per unit of time can vary greatly. Factors influencing reading rates include the technical quality of the radiographs, the prevalence of abnormalities on the radiographs, the experience of the reader, the purpose of the reading exercise and the length of the reading session.

Number of readers

It is recognized that there is considerable variation in multiple readings of some radiographs, not only from reader to reader (inter-observer variation), but also between readings by the same reader (intra-observer variation). It is recommended that, in epidemiological studies, at least two, but preferably more, readers each classify all radiographs independently.

When many radiographs are being read, intra-observer variation, i.e. variation in repeated readings by the same reader, should be assessed.

6

Appendices

The appendices have been prepared by individual experts to assist understanding of the principles and development of the ILO International Classification. They are not part of the text of the ILO (2000) International Classification of Radiographs of Pneumoconioses. The ILO wishes to express its gratitude to Dr. Kurt G. Hering, Dr. Yutaka Hosoda, Dr. Michael Jacobsen, Dr. Yukinori Kusaka, Mr. Otha W. Linton, Dr. John E. Parker, Dr. Anthony V. Proto, Dr. Hisao Shida, Dr. Gregory R.Wagner, Dr. Jerome F. Wiot and Dr. Anders Zitting for the preparation of the appendices.

Appendix A – A note on technical quality for chest radiographs of dust-exposed workers

It has long been recognized that the technique and equipment used for chest radiographic imaging of dust-exposed workers affect the radiographic appearance of pneumoconiotic lesions, and that this can influence the classification of a radiograph for pneumoconiosis. Both clinical interpretations of chest radiographs, and the use of the ILO Classification for medical screening, public health surveillance and epidemiological research, require good-quality radiographs. Consequently, readers may find it difficult to use the ILO Classification if the quality of chest radiographs is suboptimal. In some cases, it may be impossible to classify such a radiograph. Provision has been made for this contingency in section 3.1 of these *Guidelines* by the definition of technical quality grade **4** ("unacceptable for classification purposes").

Common quality faults include *underexposure* (often associated with a tendency to read more profusion than would be recognized on an optimally produced radiograph) and *overexposure* (associated with the converse tendency). Experienced readers may sometimes adjust their assessments of such radiographs to compensate, to some extent, for these perceived technical faults. Nevertheless, physicians and radiographers should strive always to obtain good-quality radiographs.

An optimal radiographic technique for the assessment of pneumoconiosis should reveal the fine detail of parenchymal markings, demonstrate clearly the costal–pleural junctions and show vascular markings through the cardiac shadow. It should be noted, however, that good contrast, required to evaluate the pulmonary parenchyma, may be suboptimal for assessment of mediastinal structures.

Methods for imaging the chest for dust-related lung diseases continue to evolve as new technologies are introduced. In view of these ongoing developments, it would be inappropriate here to attempt to provide detailed technical advice on radiographic technique and equipment. Authoritative information on these topics may be found in a number of specialist publications. A select bibliography is provided at the end of this appendix.

These *Guidelines* require that a decision on whether a radiograph is of good, or at least of acceptable, technical quality rests ultimately with the physician who classifies the radiograph. Therefore, a key general principle must be the establishment and maintenance of good communication between the physician and the radiographer, so that high-quality images, providing an adequate view of the pulmonary parenchyma and pleura, are obtained. The radiographer must be well trained and supervised, and must work in a climate that invites dialogue with the physician/reader. The physician must provide feedback to the radiographer to ensure improvement of any suboptimal images, and should be prepared to advise on quality control for the production of chest radiographs of dust-exposed workers. Physicians and radiographers should take cognizance of local regulations.

Select bibliography

American College of Radiology. *ACR Standard for the Performance of Pediatric and Adult Chest Radiography*. Reston, Va., American College of Radiology, 1997.

Commission of the European Community. *European Guidelines on Quality Criteria for Diagnostic Radiographic Images*, edited by J.H.E. Carmichael et al. Report OP-EUR 16260, Luxembourg, 1996.

Guibelalde, E., et al. "Image quality and patient dose for different screen-film combinations", in *British Journal of Radiology*, Vol. 67, No. 794, Feb. 1994, pp.166-173.

Holm, T.; Palmer, P.E.S.; Lehtinen, E. *Manual of radiographic technique: WHO Basic Radiological System*. Geneva, World Health Organization, 1986.

International Labour Office. "Appendix A. Equipment and technology: Guidance notes", prepared by H. Bohlig et al., in *Guidelines for the Use of ILO International Classification of Radiographs of Pneumoconioses*. Geneva, revised edition 1980, pp. 21-25.

Ravin, C.E.; Chotas, H.G. "Chest radiography", in *Radiology*, Vol. 204, No. 3 (Sep.), 1997, pp. 593-600.

Appendix B – Reading sheets

The reading sheets on the following pages are examples of what may be used with the ILO (2000) International Classification of Radiographs of Pneumoconioses. In some situations, clinical or epidemiological, other designs may be preferred for specific uses. The sheets illustrated here make provision for recording all features described in the Complete Classification and the Abbreviated Classification. However, they are not a formal part of the ILO International Classification.

READING SHEET FOR
COMPLETE ILO (2000) INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF PNEUMOCONIOSES

READER CODE ☐☐☐ RADIOGRAPH IDENTIFIER ☐☐☐☐☐☐☐☐☐

DATE OF READING ☐☐—☐☐—☐☐☐☐ DATE OF RADIOGRAPH ☐☐—☐☐—☐☐☐☐

TECHNICAL QUALITY

Grade 1, 2, 3 or 4 (Mark appropriate box) 1 2 3 4

If grade not 1, **Comment** *required here*

Comment on technical quality:

PARENCHYMAL ABNORMALITIES

Small opacities

Profusion (12-point scale)

0/– 0/0 0/1 1/0 1/1 1/2 2/1 2/2 2/3 3/2 3/3 3/+

(Consult standard radiographs — mark profusion subcategory.)

0/–	0/0	0/1
1/0	1/1	1/2
2/1	2/2	2/3
3/2	3/3	3/+

Affected zones

(Mark ALL affected zones)

	R	L
Upper		
Middle		
Lower		

Shape and size: p, q, r, s, t or u
(Consult standard radiographs. Two symbols required;
mark one primary and one secondary.)

	Primary		Secondary	
	p	s	p	s
	q	t	q	t
	r	u	r	u

Large opacities Mark 0 for none or mark A, B, or C 0 A B C

PLEURAL ABNORMALITIES Yes ☐ No ☐

If "No" go to *SYMBOLS

(0=None R=Right L=Left)

PLEURAL PLAQUES

Site *(Mark appropriate boxes)*		*Calcification* *(Mark)*	*Extent (chest wall; combined for in-profile and face-on)* up to ¼ of lateral chest wall = 1; ¼ to ½ of lateral chest wall = 2; > ½ of lateral chest wall = 3		*Width (optional)* (3 mm minimum width required) 3 to 5 mm = a; 5 to 10 mm = b; > 10 mm = c	
Chest wall in profile	0 R L	0 R L	0 R	0 L	R	L
			1 2 3	1 2 3	a b c	a b c
face-on	0 R L	0 R L				
Diaphragm	0 R L	0 R L				
Other site(s)	0 R L	0 R L				

COSTOPHRENIC ANGLE OBLITERATION [O] [R] [L]

DIFFUSE PLEURAL THICKENING *(Mark appropriate boxes)*		*Calcification (Mark)*	*Extent (chest wall; combined for in-profile and face-on)* up to ¼ of lateral chest wall = 1; ¼ to ½ of lateral chest wall = 2; > ½ of lateral chest wall = 3		*Width (optional)* (3 mm minimum width required) 3 to 5 mm = a; 5 to 10 mm = b; > 10 mm = c	
Chest wall in profile	[O] [R] [L]	[O] [R] [L]	[O] [R]	[O] [L]	[R]	[L]
			[1] [2] [3]	[1] [2] [3]	[a] [b] [c]	[a] [b] [c]
face-on	[O] [R] [L]	[O] [R] [L]				

*SYMBOLS

Yes [ ] No [ ]

aa at ax bu ca cg cn co cp cv di ef em es

(Circle as appropriate; if od *circled,* COMMENT *must be made below)*

fr hi ho id ih kl me pa pb pi px ra rp tb od

COMMENTS

Yes [ ] No [ ]

READING SHEET FOR
ABBREVIATED ILO (2000) INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF PNEUMOCONIOSES

READER CODE ☐☐☐ RADIOGRAPH IDENTIFIER ☐☐☐☐☐☐☐☐☐

DATE OF READING ☐☐—☐☐—☐☐☐☐ DATE OF RADIOGRAPH ☐☐—☐☐—☐☐☐☐

TECHNICAL QUALITY
Grade 1, 2, 3 or 4 (Mark appropriate box) 1 2 3 4

If grade not 1, **Comment** *required her*

Comment on technical quality:

PARENCHYMAL ABNORMALITIES

Small opacities

Profusion (4-point scale)
(Consult standard radiographs — mark profusion category) 0 1 2 3

Predominant shape and size (Consult standard radiographs) p, q, r, s, t or u (Mark only one box)

p s
q t
r u

Large opacities Mark 0 for none or mark A, B or C 0 A B C

PLEURAL ABNORMALITIES

Yes ☐ No ☐

If "No" go to *SYMBOLS

(0 = None R = Right L = Left)

Pleural thickening — PT [O] [R] [L]

Pleural calcification — PC [O] [R] [L]

***SYMBOLS**

Yes ☐ No ☐

aa at ax bu ca cg cn co cp cv di ef em es

fr hi ho id ih kl me pa pb pi px ra rp tb od

(Circle as appropriate; if **od** *circled,* COMMENT *must be made below)*

COMMENTS

Yes ☐ No ☐

Appendix C – Description of standard radiographs

The Complete Set (22 radiographs)

The ILO (2000) International Classification of Radiographs of Pneumoconioses is accompanied by 22 standard radiographs. Two of them illustrate category **0/0** profusion of small opacities. Fifteen others define small-opacity profusion categories (**1/1**, **2/2** and **3/3**), and some of the shapes and sizes of these opacities (**p**, **q**, **r**, **s**, and **t**). Large opacities (categories **A**, **B** and **C**) are shown on three additional radiographs. These 20 radiographs are described in the following table using the conventions defined in the preceding text and including Comments. The site of small opacities is shown by a tick in the boxes symbolizing the zones of the lungs, as follows:

	Right	Left
Upper	☐	☐
Middle	☐	☐
Lower	☐	☐

The two remaining standard radiographs are composite reproductions of sections from full-size chest radiographs. One depicts increasing profusion of irregular small **u**-sized opacities. The other illustrates various pleural abnormalities.

The radiographs that define the small-opacity profusion categories are copies of the same standards that were published in 1980, thus preserving continuity and consistency in the Classification. As noted in footnote 3 on page 3, the standard radiographs were chosen to demonstrate the radiographic features of the pneumoconioses, rather than to demonstrate technical quality.

The descriptions of the radiographs in the following table are the consensus views of a group of experts who reassessed the standards in the year 2000. These descriptions differ in some respects from those published in the earlier (1980) edition of the Classification. Judgements about the technical quality of the radiographs reflect familiarity with current optimal techniques and thus may appear more severe, with only six graded **1** (good). Descriptions of pleural abnormalities now follow the modified conventions that are defined in these *Guidelines* (section 3.3). The Comments in the right-hand column of the table include some additional observations by the reviewers.

The Quad Set (14 radiographs)

Also available from the ILO is a set of 14 standard radiographs that are wholly compatible with the Complete Set referred to above.[1] The Quad Set may be preferred by some users of the Classification. It includes nine of the most commonly used standard radiographs from the Complete Set (both category **0/0** examples, six showing categories **1/1**, **2/2** and **3/3** for **q/q** and **t/t** small opacities, and the composite radiograph that illustrates pleural abnormalities). The remaining five radiographs in the Quad Set are composite reproductions of quadrant sections from the other radiographs in the Complete Set. Four of them show different profusion categories for small opacities classifiable as **p/p**, **r/r**, **s/s** and **u/u**, respectively, and one shows large opacities (categories **A**, **B** and **C**).

Scientific reports that mention these *Guidelines* and the associated standard radiographs should refer to them explicitly as the ILO (2000) International Classification of Radiographs of Pneumoconioses, to avoid confusion with earlier editions of the Classification and copies of standard radiographs. The international trial, which demonstrated the general compatibility of the Quad Set with the Complete Set, showed that, when using the Quad Set, some readers identified large opacities less frequently than when they used the Complete Set. Use of the Quad Set was also associated with an increase in the frequency with which some readers described the shapes of the small opacities that they saw as predominantly irregular, rather than rounded. It is recommended, therefore, that authors of research reports should indicate which set of standard radiographs (the Complete Set or the Quad Set) was used in their studies.

[1] See footnote 1 in the foreword.

Description of standard radiographs

Standard radiograph (ILO, 2000)	Technical Quality	Parenchymal abnormalities				Pleural abnormalities					Symbols	Comments
		Profusion	Shape and size	Zones	Large opacities	Chest wall: Plaques (localized pleural thickening)	Chest wall: Diffuse pleural thickening	Costophrenic angle obliteration	Diaphragm	Calcification		
0/0 (example 1)	2	0/0	—	—	No	No	No	No	No	No	None	Quality: unsharp upper ribs. Vascular pattern well illustrated.
0/0 (example 2)	2	0/0	—	—	No	No	No	No	No	No	None	Quality: unsharp upper ribs. Vascular pattern well illustrated, but not as clearly as in example 1.
1/1 p/p	2	1/1	p/p	R L ☑ ☑ ☑ ☑ ☑ ☑	A	No	No	No	No	No	ca rp od	Quality: scapular overlap. rp in left lower zone. od in left upper and left lower zones; evaluate.
2/2 p/p	1	2/2	p/p	R L ☑ ☑ ☑ ☑ ☑ ☑	No	No	No	No	No	No	cg pi	
3/3 p/p	2	3/3	p/p	R L ☑ ☑ ☑ ☑ ☑ ☑	No	No	No	No	No	No	ca	Quality: scapular overlap. ca in right upper zone.

Description of standard radiographs

Standard radiograph (ILO, 2000)	Technical Quality	Parenchymal abnormalities: Profusion	Shape and size	Zones (R L)	Large opacities	Pleural abnormalities: Chest wall: Plaques (localized pleural thickening)	Diffuse pleural thickening	Costophrenic angle obliteration	Diaphragm	Calcification	Symbols	Comments
1/1 q/q	2	1/1	q/q	☑☑ ☑☑ ☐☐	No	No	No	No	No	No	None	Quality: overexposed; costophrenic angles excluded.
2/2 q/q	1	2/2	q/q	☑☑ ☑☑ ☑☑	No	No	No	Yes R L ☐☑	No	No	None	Right costophrenic angle appearance due to muscle slip.
3/3 q/q	2	3/3	q/q	☑☑ ☑☑ ☑☑	No	No	No	No	No	No	pi	Quality: underexposed; costophrenic angle excluded.
1/1 r/r	2	1/1	r/r	☑☑ ☑☑ ☐☐	No	No	No	Yes R L ☐☑	No	No	None	Quality: scapular overlap; unsharp lower zones. Profusion of small opacities is more marked in right lung.
2/2 r/r	2	2/2	r/r	☑☑ ☑☑ ☑☑	No	No	No	No	No	No	hi	Quality: contrast too high. hi in right paratracheal area; evaluate.

›escription of standard radiographs

›andard ›diograph ›O, 2000)	Technical Quality	Parenchymal abnormalities				Pleural abnormalities					Symbols	Comments
		Profusion	Shape and size	Zones	Large opacities	Chest wall		Costophrenic angle obliteration	Diaphragm	Calcification		
						Plaques (localized pleural thickening)	Diffuse pleural thickening					
›3 r/r	2	3/3	r/r	R L ☑ ☑ ☑ ☑ ☑ ☑	No	No	No	No	No	No	 ax ih	Quality: contrast too high. ax in right upper zone.
›1 s/t	2	1/1	s/t	R L ☑ ☐ ☑ ☑ ☑ ☑	No	No	No	No	No	No	None	Quality: unsharp areas; costophrenic angles excluded.
›2 s/s	2	2/2	s/s	R L ☐ ☐ ☑ ☑ ☑ ☑	No	No	No	No	No	No	 em pb	Quality: slightly underexposed; costophrenic angles excluded. em in upper zones. pb in left lower zone.
›3 s/s	2	3/3	s/s	R L ☑ ☑ ☑ ☑ ☑ ☑	No	No	No	No	No	No	 ho ih pi	Quality: slightly underexposed; scapular overlap. ho at right costrophenic angle See footnote 14 on page 9.

›escription of standard radiographs

ındard ›iograph ›D, 2000)	Technical Quality	Parenchymal abnormalities				Pleural abnormalities					Symbols	Comments
		Profusion	Shape and size	Zones	Large opacities	Chest wall: Plaques (localized pleural thickening)	Chest wall: Diffuse pleural thickening	Costophrenic angle obliteration	Diaphragm	Calcification		
ɪ t/t ›stophrenic ›gle obliteration	2	1/1	t/t	R L ☐ ☐ ☑ ☑ ☑ ☑	No	Yes R L ☐ ☑ face-on	No	Yes R L ☑ ☐	No	Yes R L ☐ ☑	None	Quality: scapular overlap on right, but visualization of lung and pleura not compromised. This radiograph defines the lower limit of costophrenic angle obliteration. Calcified face-on plaques at lower and mid-left chest wall.
2 t/t	1	2/2	t/t	R L ☑ ☑ ☑ ☑ ☑ ☑	No	No	No	No	No	No	None	
3 t/t	1	3/3	t/t	R L ☑ ☑ ☑ ☑ ☑ ☑	No	No	No	No	No	No	ca cp ho id ih od	ca: superior to left hilum. ho: best seen at left lower zone. od: nodule lateral to left hilum.
ɔ	—	—	—	—	—	—	—	—	—	—	—	This composite radiograph illustrates central subcategories of profusion of small opacities classifiable for shape and size as u/u.
1 u/u	—	—	—	—	—	—	—	—	—	—	—	
2 u/u	—	—	—	—	—	—	—	—	—	—	—	
3 u/u	—	—	—	—	—	—	—	—	—	—	—	

escription of standard radiographs

andard diograph .0, 2000)	Technical Quality	Parenchymal abnormalities				Pleural abnormalities					Symbols	Comments
		Profusion	Shape and size	Zones	Large opacities	Chest wall		Costophrenic angle obliteration	Diaphragm	Calcification		
						Plaques (localized pleural thickening)	Diffuse pleural thickening					
	2	2/2	p/q	R L ☑ ☑ ☑ ☑ ☑ ☑	A	No	No	No	No	No	None	Quality: high contrast; right scapular overlap obscures visualization. If concerned that right upper zone opacity could be cancer, add symbol ca.
	1	1/2	q/p	R L ☑ ☑ ☑ ☑ ☑ ☑	B	No	No	No	No	No	ax ca	ca: right lateral mid-zone nodule.
	1	2/1	q/t	R L ☑ ☑ ☑ ☑ ☑ ☑	C	No	No	No	No	No	ax bu em es ih	bu at right upper zone. em best seen at left lower zone; es at hilar and azygos node. Small opacities difficult to classify in the presence of large opacities.

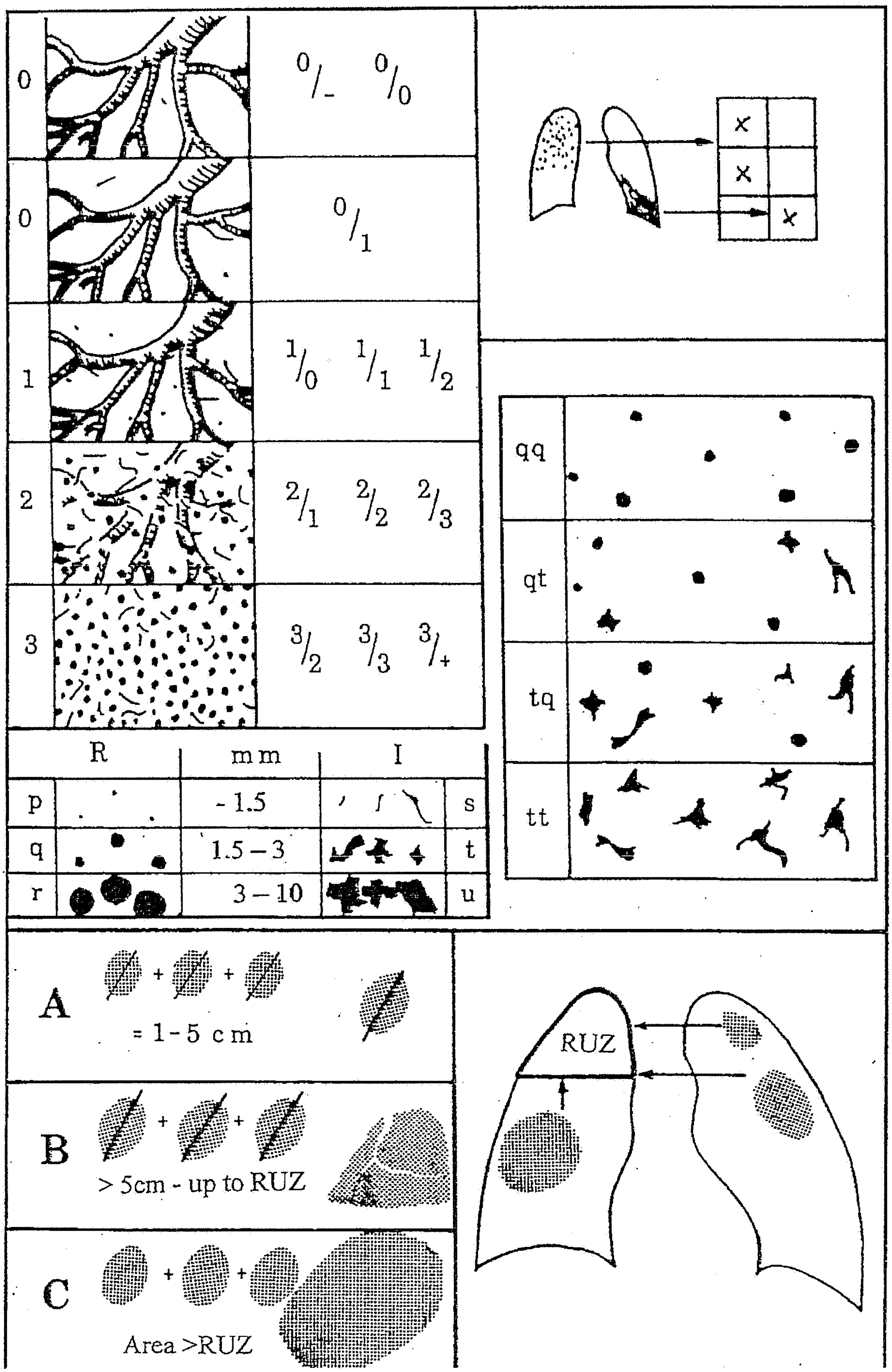
ILO (2000) Composite standard radiograph showing examples of pleural abnormalities

Upper-left section: calcified plaques at diaphragm	**Upper-right section:** calcified in-profile and face-on plaques
Lower-left section: diffuse in-profile pleural thickening with the required costophrenic angle obliteration; also diffuse face-on pleural thickening	**Lower-right section:** calcified and uncalcified face-on plaques

Appendix D – Diagrams

The diagrams on the following pages represent illustrations of radiographic features that are included in the Complete Classification. Those features are defined in the text of these *Guidelines* and by the appearances on the standard radiographs. The diagrams are intended to serve as pictorial reminders, but they are not a substitute for the standard radiographs or the written text.

Diagrams that represent symbols do not illustrate all the manifestations of the conditions defined by these symbols, for example **ca** (carcinoma), **cg** (calcified granuloma), **od** (other disease). The two drawings of appearances classifiable as **od** in this appendix represent lobar pneumonia and aspergilloma, goiter and hiatal hernia.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3 – 10
u
qq
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tq
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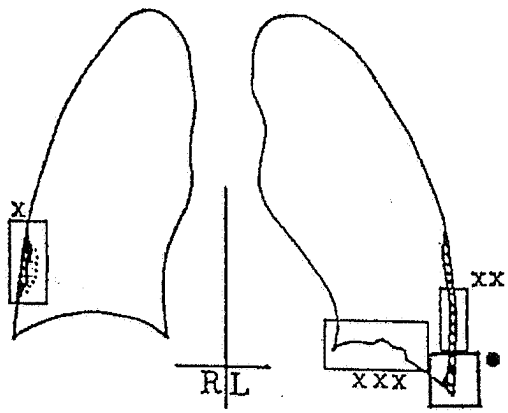
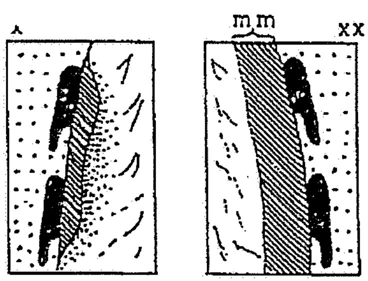
B
> 5cm - up to RUZ
C
Area >RUZ
RUZ

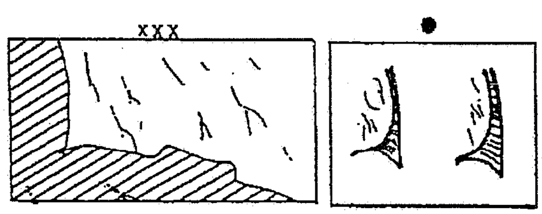
Pleural abnormalities -
(localized and diffuse pleural thickening):



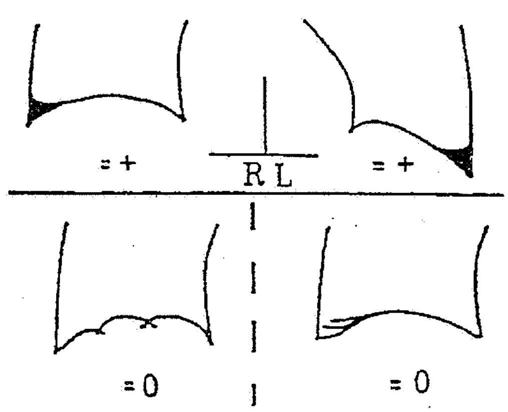
Extent:	Width:
0 = 0	a = 3-5 mm
1 = up to ¼	b = 5-10 mm
2 = ¼ - ½	c = > 10 mm
3 > ½	

See Text!



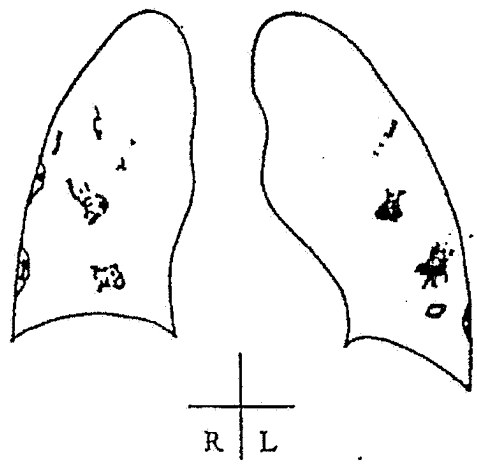


Costophrenic angle:

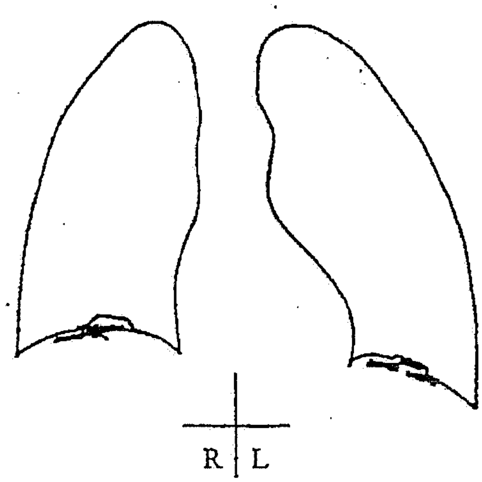


Pleural calcification:

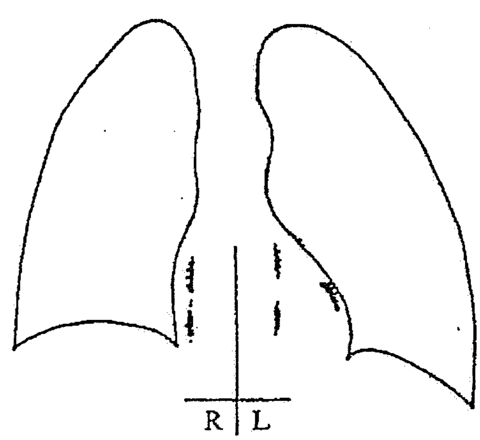
Chest wall

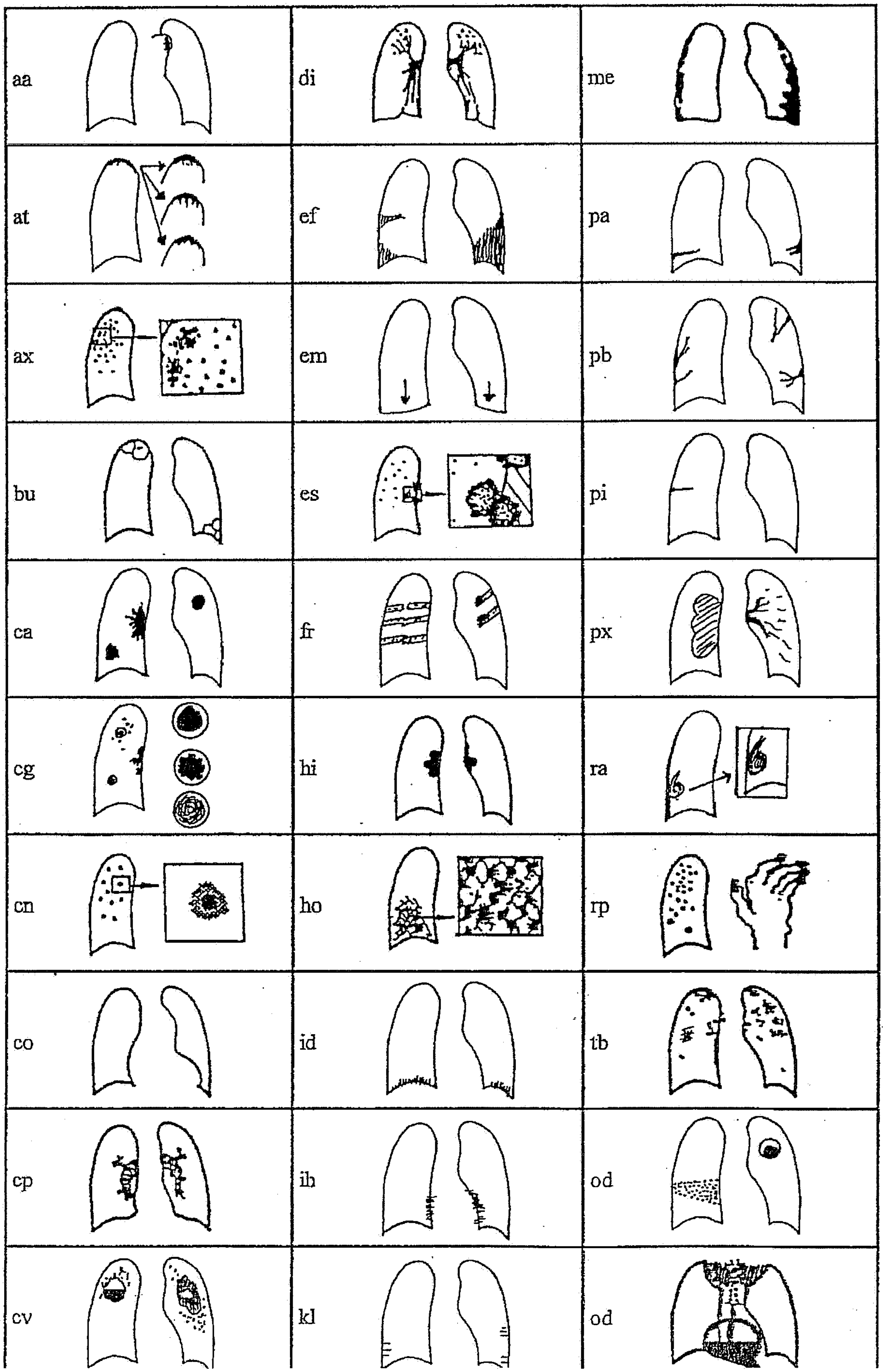


Diaphragm



Other sites

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Appendix E – Summary of details of the ILO (2000) International Classification of Radiographs of Pneumoconioses

eatures	Codes	Definitions
ECHNICAL QUALITY		
	1	Good.
	2	Acceptable, with no technical defect likely to impair classification of the radiograph for pneumoconiosis.
	3	Acceptable, with some technical defect but still adequate for classification purposes.
	4	Unacceptable for classification purposes.
		If technical quality is not grade 1, a comment must be made about the technical defect.
ARENCHYMAL ABNORMALITIES		
Small opacities		
Profusion		The category of profusion is based on assessment of the concentration of opacities by comparison with the standard radiographs.
	0/– 0/0 0/1	Category 0: small opacities absent or less profuse than category 1.
	1/0 1/1 1/2	Categories 1,
	2/1 2/2 2/3	2 and
	3/2 3/3 3/+	3 represent increasing profusion of small opacities, as defined by the corresponding standard radiographs.
Zones	RU LU RM LM RL LL	The zones in which the opacities are seen are recorded. The right (R) and left (L) thorax are both divided into three zones: upper (U), middle (M) and lower (L). The category of profusion is determined by considering the profusion as a whole over the affected zones of the lung and by comparing this with the standard radiographs – see footnote 5 on page 5 of these *Guidelines*.
Shape and size		
— rounded	p/p q/q r/r	The letters p, q and r denote the presence of small rounded opacities, with three sizes defined by the appearances on the standard radiographs: p = diameter up to about 1.5 mm; q = diameter exceeding about 1.5 mm and up to about 3 mm; r = diameter exceeding about 3 mm and up to about 10 mm.
— irregular	s/s t/t u/u	The letters s, t and u denote the presence of small irregular opacities, with three sizes defined by the appearances on the standard radiographs: s = width up to about 1.5 mm; t = width exceeding about 1.5 mm and up to about 3 mm; u = width exceeding 3 mm and up to about 10 mm.

eatures	Codes	Definitions
— mixed	p/s p/t p/u p/q p/r q/s q/t q/u. q/p q/r r/s r/t r/u r/p r/q s/p s/q s/r s/t s/u t/p t/q t/r t/s t/u u/p u/q u/r u/s u/t	For mixed shapes (or sizes) of small opacities, the predominant (primary) shape and size is recorded first. The presence of a significant number of another shape and size (secondary) is recorded after the oblique stroke.
.arge opacities	0 A B .C (0 = no large opacities)	One large opacity is defined as an opacity having the longest dimension exceeding 10 mm. Categories of large opacities are defined below. These definitions take precedence over the examples of large opacities illustrated on standard radiographs. Category A: one large opacity having the longest dimension up to about 50 mm, or several large opacities with the sum of their longest dimensions not exceeding about 50 mm. Category B: one large opacity having the longest dimension exceeding 50 mm but not exceeding the equivalent area of the right upper zone, or several large opacities with the sum of their longest dimensions exceeding 50 mm but not exceeding the equivalent area of the right upper zone. Category C: one large opacity which exceeds the equivalent area of the right upper zone, or several large opacities which when combined exceed the equivalent area of the right upper zone.
ᑊLEURAL ABNORMALITIES		Three types of pleural abnormalities are recognized: pleural plaques (localized pleural thickening), costophrenic angle obliteration and diffuse pleural thickening. These abnormalities are recorded as absent (0) or present. If present they are recorded separately for the right (R) and left (L) sides.
ᑊleural plaques (localized pleural hickening)		
Chest wall		Pleural plaques on the chest wall are recorded separately as "in-profile" or "face-on". A minimum width of about 3 mm is required for an in-profile plaque to be recorded as present. The presence or absence of calcification is also noted separately for in-profile and face-on plaques. When calcification is seen, a plaque is also recorded as present at that site. For optional recording of width of an in-profile plaque, see footnote 8 on page 6.
in-profile	0 R L	
— calcification	0 R L	
— width (optional)	R(a, b, c) L(a, b, c)	
face-on	0 R L	
— calcification	0 R L	
extent	R(1, 2, 3) L(1, 2, 3)	Extent refers to the total length of involvement with respect to the projection of the lateral chest wall for in-profile and face-on plaques combined: 1 = total length up to ¼ of the projection of the lateral chest wall; 2 = total length exceeding ¼ and up to ½ of the projection of the lateral chest wall; and 3 = total length exceeding ½ of the projection of the lateral chest wall.
Diaphragm	0 R L	
— calcification	0 R L	When calcification is seen, a plaque is also recorded at that site.
Other sites	0 R L	Other sites include the mediastinal pleura in the para-spinal or para-cardiac locations.
— calcification	0 R L	When calcification is seen, a plaque is also recorded at that site.

'eatures		Codes	Definitions
;ostophrenic angle obliteration		0 R L	The lower limit for costophrenic angle obliteration is defined by the standard radiograph showing profusion category **1/1 t/t**.
)iffuse ıleural hickening	Chest wall		Diffuse pleural thickening extending up the lateral chest wall is recorded only in the presence of an obliterated costophrenic angle. If present, diffuse pleural thickening is recorded separately for the right and left sides when seen in-profile and when seen face-on. The presence or absence of calcification is noted in both cases. For optional recording of width of in-profile diffuse pleural thickening, see footnote 8 on page 6.
	in-profile	0 R L	
	— calcification	0 R L	
	— width (optional)	R(a, b, c) L(a, b, c)	
	face-on	0 R L	
	— calcification	0 R L	
	extent	R(1, 2, 3) L(1, 2, 3)	Extent refers to the total length of involvement with respect to the projection of the lateral chest wall for in-profile and face-on varieties combined: 1 = total length up to ¼ of the projection of the lateral chest wall; 2 = total length exceeding ¼ and up to ½ of the projection of the lateral chest wall; and 3 = total length exceeding ½ of the projection of the lateral chest wall.
;YMBOLS			The definition of each symbol should be understood as being preceded by an introductory qualifying word or phrase such as "changes indicative of", "opacities suggestive of", or "suspect".
		aa	atherosclerotic aorta
		at	significant apical pleural thickening
		ax	coalescence of small opacities
		bu	bulla(e)
		ca	cancer: thoracic malignancies excluding mesothelioma
		cg	calcified non-pneumoconiotic nodules (e.g. granuloma) or nodes
		cn	calcification in small pneumoconiotic opacities
		co	abnormality of cardiac size or shape
		cp	cor pulmonale
		cv	cavity
		di	marked distortion of an intrathoracic structure
		ef	pleural effusion
		em	emphysema
		es	eggshell calcification of hilar or mediastinal lymph nodes
		fr	fractured rib(s) (acute or healed)
		hi	enlargement of non-calcified hilar or mediastinal lymph nodes
		ho	honeycomb lung
		id	ill-defined diaphragm border
		ih	ill-defined heart border
		kl	septal (Kerley) lines
		me	mesothelioma
		pa	plate atelectasis
		pb	parenchymal bands
		pi	pleural thickening of an interlobar fissure
		px	pneumothorax

ɘatures	Codes	Definitions
	ra	rounded atelectasis
	rp	rheumatoid pneumoconiosis
	tb	tuberculosis
	od	other disease or significant abnormality
OMMENTS	Y (= Yes) N (= No)	In addition to comments about the technical quality of the radiograph (see above), comments are also required if the symbol od (other disease) is recorded, and to identify any part of the reading of a chest radiograph which is believed by a reader to be probably or certainly not dust related. Comments should also be recorded to provide other relevant information.

Appendix F – Participants in ILO-convened meetings leading to the revised (2000) edition of the Classification

Meeting of Discussion Group at ILO Headquarters, Geneva, 6-7 November 1989

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Dr. Alois David
Dr. Michel Lesage

Meeting of Discussion Group in Kyoto, Japan, 15-16 October 1997

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Meeting of Discussion Group at the Office of the American College of Radiology, Reston, Virginia, United States, 20-21 March 1998

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Meeting of Discussion Group at the ILO Branch Office, Washington, DC, United States, 26 October 2000

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ILO Secretariat

Dr. Benjamin O. Alli

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Dr. Anders J. Zitting, Finnish Institute of Occupational Health, Helsinki

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Professor Dominique Choudat, Université Paris V, Faculté de médecine Cochin, Paris
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[1] As of 1 January 1993. Prior to that date, Czechoslovakia.

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Professor Kazimierz Marek, Institute of Occupational Medicine and Environmental Health, Sosnowiec
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Dr. Susan Weber, Pulmonary and Critical Care Medicine, West Virginia University, Morgantown, West Virginia

[1] As of 1 January 1993. Prior to that date, Czechoslovakia.

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REVISED EDITION 2000

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The revised edition retains the same general principles as former editions, but it clarifies some ambiguities which have come to light. Rules for classifying pleural abnormalities have also been revised. These changes are based on a continuing process of review, including discussion at the Ninth International Conference on Occupational Respiratory Diseases in 1997, and controlled trials of new composite standard radiographs between 1992 and 1995.

For greater convenience, the radiographs accompanying the revised (2000) *Guidelines* comprise two standard sets: the Complete Set (22 radiographs) and the "Quad" Set (14 radiographs). The latter includes quadrant sections of some radiographs in the Complete Set.

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The Clinical Diagnosis of Asbestosis in This Century Requires More Than a Chest Radiograph*

Robert M. Ross, MD, FCCP

Asbestosis can cause significant impairment and even death. It is also a well-recognized risk factor for the development of lung cancer. However, asbestosis is usually diagnosed on clinical grounds without the aid of pathology. Many physicians and researchers believe that in asbestos-exposed individuals with adequate latency, chest radiographic findings that are compatible with asbestosis are sufficient for the diagnosis. In order to determine whether this approach is reasonable, the positive predictive value of the chest radiograph for the diagnosis of pathologic asbestosis must be determined. This requires information about the prevalence of asbestosis, and the sensitivity and specificity of the chest radiograph in its diagnosis. In this article, the sensitivity and specificity of the chest radiograph in diagnosing asbestosis is determined from a literature analysis. The prevalence of asbestosis among present-day cohorts, such as construction workers and petrochemical workers, is assessed based on the relative risk of lung cancer in patients with asbestosis and the overall relative risk of lung cancer in these occupationally asbestos-exposed cohorts. The results indicate a positive predictive value for abnormal chest radiograph findings alone to be significantly < 50%. Therefore, the chest radiograph is inadequate as the sole clinical tool to be used to diagnose asbestosis in these cohorts. However, when rales and a low diffusing capacity of the lung for carbon monoxide are also present, the diagnosis of asbestosis on clinical grounds can be made with reasonable confidence. ***(CHEST 2003; 124:1120–1128)***

Key words: asbestos; asbestosis; chest radiograph; diagnosis; diffusing capacity; lung cancer; rales

Abbreviations: DLCO = diffusing capacity of the lung for carbon monoxide; HRCT = high-resolution computed tomography; ILO = International Labour Organization

Asbestosis is a form of diffuse interstitial pulmonary fibrosis. It is caused by the inhalation of excessive amounts of asbestos fibers that are within certain size and aerodynamic shape ranges. It can cause significant impairment, or even death, and is a well-recognized risk factor for the development of cancer of the lung. However, frequently a diagnosis must be made in a particular person without the aid of pathology. That is, asbestosis must often be diagnosed on clinical grounds. The American Thoracic Society, in its 1986 position paper on the diagnosis of nonmalignant diseases related to asbestos,[1] reviewed, in a general way, the factors to consider when trying to diagnose asbestosis clinically. In a summary paragraph, it suggested that, in individuals with appropriate exposure and latency, the chest radiograph is the most important tool in diagnosis when pathology specimens are not available. Many physicians have thus concluded that the finding of a chest radiograph compatible with asbestosis in a patient with previous asbestos exposure is sufficient to diagnose asbestosis with all its attendant associated risks of morbidity and mortality. Furthermore, many epidemiologic studies have also used the finding of a chest radiograph compatible with asbestosis as a surrogate for asbestosis. In short, many people think that the presence of a mildly abnormal chest radiograph finding is compatible with asbestosis (International Labor Organization [ILO] grade, 1/0 or 1/1)[2] in asbestos-exposed individuals is, more likely than not, indicative of pathologic asbestosis. That is, in asbestos-exposed individuals with adequate exposure and latency a chest radiographic finding of ILO grade 1/0 or 1/1 has a positive predictive value for pathologic asbestosis of > 50%.

In order to calculate the positive predictive value of a test, it is necessary to determine the prevalence of the disease in the population at risk, as well as the sensitivity and specificity of the test. In this article,

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which is based on an analysis of the literature, the prevalence of pathologic asbestosis among present-day North American cohorts in the construction and petrochemical industries, the members of which have previously been exposed to asbestos, can be estimated. The sensitivity and specificity of the chest radiograph in diagnosing diffuse interstitial pulmonary fibrotic diseases such as asbestosis also can be approximated. Using these values, the positive predictive value of the chest radiograph for diagnosing pathologic asbestosis can be determined. The results show this to be significantly < 50% among individuals in these cohorts. Therefore, the chest radiograph should not be used as the sole diagnostic tool as it will be wrong more often than it will be right.

Mortality Risk From Lung Cancer in Various Asbestos-Exposed Cohorts

Occupational exposure to asbestos is a well-recognized risk factor for primary cancer of the lung. However, the size of the risk varies quite markedly depending on the cohort and the date of the study (earlier studies generally reflect the effects of much heavier exposure). For example, in a study of insulators published in 1979, lung cancer mortality was increased more than four times compared to control subjects,[3] whereas in a study[4] of shipyard workers in Hawaii, the incidence of lung cancer was only 40% greater among workers with at least 15 years of asbestos exposure compared to control subjects. A 1999 meta-analysis reviewed 69 asbestos-exposed occupational cohorts.[5] These cohorts consisted of individuals who often were involved in the mining or manufacturing of asbestos products or were members of heavily exposed groups, such as shipyard workers or insulators. The meta-standard mortality ratio increase for lung cancer, considering latency, was 63%. However, studies of other cohorts such as petrochemical workers[6] and steelworkers,[7] for example, often have found no increase in lung cancer.

Presently, the majority of workers who have been occupationally exposed to asbestos are not those in the primary asbestos industries, such as mining or the manufacture of asbestos-containing products, but are workers who used these products.[8] Table 1 lists the mortality risk ratios for lung cancer deaths among construction workers and petrochemical workers in North America obtained from a MedLine search of large cohorts published since 1990.[6,9–24]

Table 1—***Death From Lung Cancer From Various Studies of People Exposed to Asbestos****

Study/Year	Description	Patients, No.	Deaths, No.	Lung Cancer Deaths, No.	Mortality Ratio, %	Study Type
Robinson et al[9]/1995	Construction industry		61,682	5,944	114	PMR
Stern et al[10]/1995	Construction laborers		11,685	1,208	120	PMR
Robinson et al[11]/1996	Union carpenters		27,362	2,726	122	PMR
Satin et al[12]/1996	Oil refinery workers	17,844	6,799	423	92	SMR
Tsai et al[13]/1996	Maintenance employees in a refinery and petrochemical plant	2,504	725	68	81	SMR
Cooper et al[6]/1997	Texas refinery and chemical manufacturing workers	92,318		1,388	84	SMR
Band et al[14]/1997	Pulp and paper mill workers	30,157	4,074	351	109	SMR
Stern and Haring-Sweeney[15]/1997	Construction operating engineers		15,843	1,915	126	PMR
Stern et al[16]/1997	Construction iron workers		13,301	1,523	128	PMR
Raabe et al[17]/1998	Maintenance refinery workers	5,360	1,559	109	120	SMR
Dement et al[18]/1998	Union refinery workers		2,985	206	105	PMR
Wang et al[19]/1999	North Carolina construction workers		29,544	3,023	113	PMR
Robinson et al[20]/1999	Electrical workers involved in construction		31,068	2,977	117	PMR
Steenland and Palu[21]/1999	Union painters	42,170	18,259	1,746	123	SMR
Lewis et al[22]/2000	Refinery workers	9,266	2,905	221	96	SMR
Stern et al[23]/2000	Roofers and waterproofers		11,144	1,071	139	PMR
Stern et al[24]/2001	Plasterers and cement workers		12,873	1,386	139	PMR

*SMR = standard mortality ratio; PMR = proportional mortality ratio. Total Lung Cancer deaths from all studies, 26,285; expected lung cancer deaths, 22,569; mortality ratio, 116.

These studies find a range of about 0 to 40% increased risk of lung cancer in these cohorts with an average of about 16% over unexposed control subjects. However, it should be remembered that not all of this increased risk may be due solely to asbestos. Most of these studies were not controlled for smoking or other potential carcinogens in the workplace, which also could lead to increased mortality from lung cancer.

Risk of Lung Cancer Associated With Asbestosis

Pathologic asbestosis is associated with a significant increase in lung cancer risk. In one study, an approximate fivefold increase in lung cancer was found among an insulator cohort.[25] Later, autopsy studies[26] on this group of lung cancer patients found that virtually all had asbestosis. Hughes and Weill[27] found that in a cohort of workers producing asbestos-containing cement and pipe covering those with radiographic evidence of asbestosis had a lung cancer risk that was more than four times that of the control population, and Liddell and McDonald[28] found a risk of asbestosis that was 3.5 times that of control subjects among Quebec asbestos workers who had radiographic evidence of asbestosis. In a study[29] of people who had asbestosis and were reported to the Finnish Registry of Occupational Diseases, there was an increase of more than sixfold in the incidence of lung cancer. Other studies[30] of people who were "certified" to have asbestosis by various entities also have found a marked increase in mortality from lung cancer. A 1996 study[31] of asbestosis patients found an overall relative risk of 5.9.

Other forms of diffuse interstitial pulmonary fibrosis, which are pathologically similar to asbestosis, also are associated with an increased risk of lung cancer. For example, in a study[32] of people with diffuse interstitial pulmonary fibrosis associated with scleroderma, the lung cancer risk was five times that of control subjects. Another study[33] of people with cryptogenic fibrosing alveolitis also found a markedly elevated lung cancer risk.

The exact risk of lung cancer that is associated with asbestosis depends on many factors that have not yet been completely elucidated. These may include exposure amount, intensity, duration, and host factors. The degree of fibrosis, fiber type, and smoking history also play a significant role.[34,35]

Prevalence of Asbestosis

The prevalence of pathologic asbestosis has not been accurately determined for asbestos-exposed workers. This would require the examination of lung tissue from a large number of randomly selected people, which is not feasible. Furthermore, the definition of asbestosis has to be determined. Is it solely based on pathology or does there have to be some physiologic dysfunction? Furthermore, what is the minimal amount of pathologic abnormality that is associated with an increased risk of lung cancer? These issues have not been resolved. However, the relationship between asbestosis and an increased risk of lung cancer has been studied in some detail, as was discussed in the previous section. Using this knowledge, an estimate of the prevalence of this degree of asbestosis can be obtained. Based on the overall lung cancer risk, as well as on the risks related to asbestosis and to asbestos exposure alone, an assessment of the prevalence of pathologic asbestosis that leads to an increased risk of lung cancer in the population that is at risk can be obtained. Based on the articles previously cited, the overall increase in lung cancer risk among workers such as those in the construction industry and petrochemical industry is about 16%. In addition, as previously discussed, the presence of a diffuse interstitial pulmonary fibrotic disease such as asbestosis is associated with a 3.5-fold to more than sixfold increased risk of lung cancer over that of control subjects. Using an overall risk of lung cancer of 116% and a risk of lung cancer associated with asbestosis of 400%, then, if the rest of the asbestos-exposed population were at no increased lung cancer risk, about 5% of the workers would have asbestosis ($400X + 100[1 - X] = 116$, and $X = 0.053$). Whether asbestos exposure in itself is a cause of the increased lung cancer risk or whether it is through the development of asbestosis is a current subject of debate.[36–38] If the risk of developing lung cancer in asbestos-exposed workers who do not have asbestosis is greater than that for similar unexposed control subjects, that is, if asbestos increases lung cancer risk even without the presence of asbestosis, the number of asbestosis patients must be even lower than in the previous calculation. For example, if the lung cancer risk were 10% higher than normal for asbestos-exposed persons without asbestosis, then approximately 2% of that exposed population would have asbestosis ($400X + 110[1 - X] = 116$, and $X = 0.02$). If the risk of developing lung cancer among asbestosis patients were > 400% of unexposed control subjects, the prevalence of asbestosis would be lower than that in the previous examples. Similarly, if some of the increase in lung cancer risk were due to factors other than asbestos exposure, such as a higher prevalence of smoking, smoking more, or exposure to other potential carcinogens in the workplace, the prevalence of asbestosis would also be less. It is well-recognized that construction workers smoke more than the general population.[39] If, for example, the prevalence of smokers in these cohorts were 5% greater than in the general population, if the increased risk of lung cancer that was associated with smoking were 15-fold compared to that in nonsmokers, and if the prevalence of smokers in the general population were 30%, then, utilizing calculations popularized by Axelson,[40] the relative risk of lung cancer for the group would be 113. Therefore, the increased risk due to asbestos exposure could be no > 3% and the prevalence of asbestosis would be ≤ 1%. Taking these factors into account, a reasonable estimate of the prevalence of asbestosis in these types of cohorts would be about 1 to 5%.

Sensitivity and Specificity of the Chest Radiograph in the Diagnosis of Asbestosis

The chest radiograph has long been used as an important tool in the diagnosis of diffuse interstitial pulmonary fibrotic diseases such as asbestosis. Extensive disease can usually be accurately detected by a well-trained radiologist or physician. Of course, it is necessary to exclude diseases that radiologically can be confused with diffuse interstitial pulmonary fibrosis, such as congestive heart failure or lymphangitic spread of malignancy. Also, the differential diagnosis of interstitial lung diseases must be kept in mind. It should be remembered that asbestos-exposed individuals are not immune from other forms of interstitial lung disease.[41,42] If doubt exists and a patient is significantly symptomatic, tissue biopsy is appropriate.

The chest radiograph is problematic, however, when trying to diagnose minimal or mild disease. Is a radiographic finding of a mild increase in interstitial lung markings (*ie*, a mild increase in small, irregular opacities [ILO grade, 1/0 and 1/1]) adequate by itself to diagnose asbestosis? Although chest radiographic findings usually are abnormal in patients with asbestosis, about 10 to 15% of the time they may be relatively normal,[26,43] which yields a sensitivity of 85 to 90%. Furthermore, many factors other than asbestos exposure can lead to a mildly abnormal chest radiographic finding, affecting its specificity. These factors include, for example, radiographic technique, aging, obesity, smoking, presence of COPD, and exposure to various other fibrogenic and nonfibrogenic dusts.[44] In addition, the radiologic diagnosis of *mildly abnormal* has a rather large interobserver variation. For example, in one study[45] in which 23 "B-readers" certified by the National Institute of Occupational Safety and Health evaluated 105,029 chest radiographs for the assessment of asbestosis among naval personnel, there was a 20-fold difference in the prevalence of positives findings (ILO grade, ≥ 1/0) between the extreme readers, and the average prevalence was 2.4%. Welch et al[46] reviewed the interobserver variation in chest radiograph interpretation of pneumoconiosis, finding that among the same 119 chest radiographs that were read by six qualified readers, the number that were read as being positive for asbestosis (ILO grade, ≥ 1/0) varied from 24 to 91%. This problem, of course, significantly affects sensitivity and specificity. If, in fact, 91% of the group actually had asbestosis, the individual who found it in only 24% would exhibit a very poor sensitivity of, at best, 24 of 91 patients (26%). Conversely, if 24% were the correct figure, the individual who diagnosed it in 91% of the people would exhibit very poor specificity of, at best, 9 of 76 patients (12%).

The chest radiograph may also be mildly abnormal among people who have never been exposed to asbestos and who do not have any type of diffuse interstitial pulmonary fibrosis. Epstein et al[47] found in a hospital study of 200 consecutive admission chest radiographs that were read according to the 1980 ILO scale, 11% of the radiographs were read as being positive for asbestosis (ILO grade, ≥ 1/0) with no documentable dust exposure or other specific medical etiology that would explain the presence of the lung opacities. Zitting et al[48] found in a radiographic survey of 7,095 radiographs that among the 3,494 people who were unlikely to have been exposed to asbestos there was an 11.7% incidence of their chest radiographs being read as having abnormal findings (ILO grade, ≥ 1/0). In a literature analysis of many studies performed in the United States and Europe, where radiographs were read according to the 1980 ILO standard, the number of radiographs that were read as being positive for asbestosis (ILO grade, ≥ 1/0) among people who had not been exposed to asbestos varied from 0.21 to 11.7%. A meta-analysis[49] of the published data yielded a population prevalence of 5.3%. These studies suggested that with qualified readers a specificity of 90 to 95% for the chest radiograph would be the best that could be expected.

Positive Predictive Value of the Chest Radiograph Alone

From these previous discussions, reasonable estimates of asbestosis prevalence among present-day construction or petrochemical workers, as well as the sensitivity and specificity of the chest radiograph in diagnosing asbestosis, can be made. From this, the positive predictive value of the chest radiograph can be obtained. The prevalence of asbestosis in this at-risk population could be expected to be about 1 to 5%. In addition, from the previous discussion, at least 5 to 10% of the time the chest radiograph finding may be abnormal (ILO grade, ≥ 1/0) without the presence of asbestosis. This represents a specificity of approximately 90 to 95%. Furthermore, the sensitivity of chest radiographs for asbestosis is about 85 to 90%. From these values, the positive predictive value of a positive chest radiograph can be determined with the following formula:

$$PPV = \frac{1}{1 = \left(\frac{1-spec}{sens}\right)\left(\frac{1}{prev}-1\right)}$$

where PPV is the positive predictive value, spec is specificity, sens is sensitivity, and prev is the prevalence in the at-risk population.

Using a prevalence of 5%, a sensitivity of 90%, and a specificity of 93%, the positive predictive value of a positive chest radiograph alone (ILO grades, 1/0 and 1/1) is about 40%. If the prevalence of asbestosis is 3%, the positive predictive value of the chest radiograph alone is only 28%. It should be mentioned that in cohorts with less exposure to asbestos, the prevalence of asbestosis will be even lower, and so the positive predictive value of an abnormal chest radiograph will also be lower. On the other hand, for cohorts with a high prevalence of asbestosis, such as the insulators studied by Selikoff and coworkers,[3] a radiograph with an ILO reading of 1/0 or 1/1 may have a positive predictive value > 50%. However, using a chest radiograph as the sole clinical determinant of asbestosis in most present-day asbestos-exposed cohorts such as construction or refinery workers is inaccurate at best, with well over half the people probably not actually having the disease.

Furthermore, a diagnosis of asbestosis made solely on the basis of a mildly abnormal chest radiograph may have adverse consequences. Patients may be labeled with a potentially serious disease that they do not have, which leads to unnecessary concern. These people also may ascribe symptoms to this incorrect diagnosis and may not seek medical assistance for potentially treatable problems such as COPD, asthma, or ischemic heart disease.

The mildly abnormal chest radiograph also adds confusion to the understanding of asbestos-related diseases. It is well-recognized that smokers have a higher incidence of chest radiographs showing mild increases in lung markings or so-called *dirty lungs*.[50] This, at least in part, results from the presence of chronic bronchitis and COPD. These are the people who are at highest risk for lung cancer, not only because they smoke but also because, among smokers, those with bronchitis and airflow obstruction are at a higher lung cancer risk than are comparable smokers without these findings.[51] In other words, the mildly abnormal chest radiograph tends to select people who are at higher risk for lung cancer even when controlled for smoking. Therefore, many people with a mildly abnormal chest radiograph (*ie*, ILO grade, 1/0 and 1/1) may have an increased risk of lung cancer but not because of asbestos or even because of asbestosis. This adds confusion to studies that attempt to assess the lung cancer risk from asbestosis that has been diagnosed solely on the basis of a chest radiograph.

In conclusion, utilizing the chest radiograph for the detection of asbestosis among asbestos-exposed cohorts such as construction and refinery workers has too low a true-positive rate to be relied on as the sole diagnostic tool in obtaining a reasonably accurate diagnosis.

Other Imaging Techniques

High-resolution CT (HRCT) scans of the chest are better than chest radiographs for the evaluation of asbestosis. They are more sensitive and more specific. However HRCT scans also can miss pathologic asbestosis. Furthermore, minimal changes on HRCT scans are nonspecific and often do not indicate fibrosis.[52,53] Even if the sensitivity and specificity increased to 95%, the positive predictive value of the HRCT scan alone would be only 50% if the prevalence of asbestosis were 5%, and 37% if the prevalence were 3%. Although HRCT scanning holds some promise, adequate information is not yet available to determine its positive predictive value in the diagnosis of asbestosis.

Usefulness of the History, Physical Examination, and Other Physiologic Tests in Diagnosing Asbestosis

In its position statement regarding nonmalignant disease related to asbestos,[1] the American Thoracic Society also mentioned that it is important to obtain a good occupational history and that rales, restriction, and a diffusing capacity of the lung for carbon monoxide (DLCO) below the limit of normal are of recognized value in diagnosing asbestosis. These will now be discussed.

History

Taking a good occupational history is important because it helps to place the patient in certain risk groups. By obtaining an adequate work history, a reasonable estimate of lung cancer risk and, therefore, a prevalence of asbestosis for that person can be obtained from epidemiologic studies of similar cohorts.

Rales

Characteristic rales or crackles of "Velcro" or "dry" quality have been found in approximately 70 to 90% of patients with pathologic diffuse interstitial pulmonary fibrosis diseases such as asbestosis. Epler et al,[43] studying people with interstitial lung disease, even those with a relatively normal chest radiograph finding, found rales in 71% of cases. Tukjainen et al[54] found rales in 94% of people with diffuse interstitial pulmonary fibrosis. Bouros et al[55] found rales in 85% of his group of patients with fibrosing alveolitis associated with systemic sclerosis. Bjoraker et al[56] found rales in 80% of their group of patients with idiopathic pulmonary fibrosis, and Daniil et al[57] found rales in 87% of patients. Murphy and Sorensen[58] found rales in 83% of pipe coverers with clubbing (and asbestosis). Shirai et al[59] found rales in 95% of the asbestos workers with abnormal chest radiographic findings that they studied. Furthermore, rales are an early finding and often are present before the chest radiograph becomes significantly abnormal.[59,60] Rales are not under volition and, when found by a well-trained physician, are quite specific.[61] It is distinctly uncommon to have pathologic asbestosis without the presence of rales.

Restriction

With significant diffuse interstitial pulmonary fibrosis, the lungs shrink, leading to reduced vital capacity and lung volumes, such as total lung capacity (restriction). However, the normal range for these parameters is quite large, so small changes may not be detected on cross-sectional testing. Furthermore, the vital capacity test is voluntary, and results can be abnormal due to effort or understanding. Also, many other medical disorders other than diffuse interstitial pulmonary fibrosis lead to restriction. Therefore, although the finding of restriction on pulmonary function testing is seen in approximately 50 to 60% of patients with diffuse interstitial pulmonary fibrosis diseases, such as asbestosis, it is too nonspecific to be used as a sole diagnostic tool and is relatively insensitive for the detection of mild fibrosis.

DLCO

The DLCO test, however, is very sensitive for the presence of diffuse interstitial pulmonary fibrosis. This is because this disorder first and most extensively affects the smallest airways, alveolar ducts, alveoli, and microcirculation where gas exchange occurs. The disease alters the anatomy so that the matching of ventilation with pulmonary blood flow is less than optimal. The overall result is ventilation-perfusion mismatching and gas exchange abnormalities, which the DLCO test is exquisitely sensitive at assessing. Although it is not highly specific and many factors may lead to it being low, a normal diffusing capacity test result is rarely found with the presence of a pathologic diffuse interstitial fibrotic diseases, such as asbestosis. In fact, the DLCO is reduced in 70% to > 90% of cases.

In Table 2 the findings from several studies regarding rales and DLCO in patients with diffuse interstitial pulmonary fibrosis are reviewed.[62] It can be seen that rales and reduced DLCO are very frequently seen in patients with diffuse interstitial pulmonary fibrotic diseases, such as asbestosis. In fact, some studies have found them more sensitive than HRCT scanning,[63] and Markowitz et al[64] found that abnormal findings of pulmonary function tests

Table 2—*Findings From Studies of Patients With Interstitial Pulmonary Fibrosis**

Study/Year	Group	Patients, No.	Clubbing, %	Rales, %	Reduced VC, %	Reduced DLCO, %
Murphy and Sorensen[58]/1973	Asbestos pipecoverers with clubbing	12	100	83		
Epler et al[43]/1978	Various ILDs	458		71†	57	71
Tukjainen et al[54]/1983	IPF	100	46	94	70	90–95
Bjoraker et al[56]/1998	IPF (UIP/NSIP and others)	104	25	80	73	90–95
Daniil et al[57]/1999	IPF (UIP/NSIP)	30	67	93	Most	80–85
Shirai et al[59]/1981	Asbestosis	21		95		
King et al[62]/2001	IPF (biopsy-proven UIP)	85			70–75	80–85
Bouros et al[55]/2002	ILD (associated with systemic sclerosis)	74		85	57	97

*IPF = idiopathic pulmonary fibrosis; UIP = usual interstitial pneumonia; NSIP = nonspecific interstitial pneumonia; ILD = interstitial lung disease.

†Interstitial pneumonia.

and physical examinations significantly raised the risk of dying of asbestosis in a cohort of insulators.

The Clinical Diagnosis of Asbestosis

How can these various clinical diagnostic findings be used in order to diagnose asbestosis within a reasonable degree of certainty without too many false-positive diagnoses or too many false-negative diagnoses when lung tissue is not available? The chest radiograph is positive in approximately 90% of cases. Furthermore, pleural plaques are often present in patients with asbestosis.[65] Rales occur in approximately 70 to 90% of cases, and a reduced DLCO occurs in about 80 to 90% of cases. Conversely, many chest radiographs will be interpreted as mildly abnormal (ILO grade, 1/0 and 1/1) but will not be due to asbestosis or diffuse interstitial pulmonary fibrosis. Dry or velcro rales are quite specific for diffuse interstitial pulmonary fibrosis, but rales from mucus in the airways, congestive heart failure, or even mild basilar atelectasis occasionally can be confused with the rales of fibrosis. The DLCO may be reduced secondary to technical factors or other medical problems and is by no means specific for diffuse interstitial pulmonary fibrosis. The goal in terms of clinical diagnosis is to find whether these tests together have a high enough specificity with adequate sensitivity so that the positive predictive value when all these test results are abnormal will be significantly $> 50\%$ without missing too many people who have the disease.

The sensitivity and specificity of chest radiograph, rales and DLCO for the diagnosis of asbestosis can be estimated. For chest radiographs, the sensitivity is approximately 90%, while the specificity is 90 to 95% (therefore, 93% specificity will be chosen). For DLCO, the sensitivity is approximately 85%. By definition, the lower limit of normal for the test is such that 95% of healthy people have a result equal to, or higher than, that value (*ie*, a specificity of 95%). However, technical factors and other disorders also lead to a reduced DLCO. There are only a few disorders that lead to an increase in DLCO, so the test is rarely falsely high. The actual specificity for DLCO in diagnosing asbestosis is not known with certainty. However, even if 10% of the study population had other disorders leading to a reduced DLCO, the specificity of the test would be about 85%. For rales, based on values from the studies presented, a sensitivity of 80% would be appropriate. Taking into account rales due to mucus in the airways, congestive heart failure, and technical factors, the specificity should be not much lower than 75 to 80%. So, a specificity of 75% will be chosen.

The interdependence of the various tests has not been carefully examined. If each test were independent of the others, the overall specificity of these tests together would be $> 99\%$. For example, from the previous discussion the chest radiograph could be expected to be normal in about 93% of people who do not have asbestosis. If the tests were completely independent, DLCO would be expected to be within normal limits in about 85% of the remaining 7%, leaving only about 1.05%. Rales would be absent in about 75% of these, leaving only 0.26% of people with asbestosis who would be missed by all three tests (*ie*, $0.93 + 0.85 \times 0.07 + 0.75 \times 0.0105 = 99.74\%$). It is reasonable to assume that the tests are relatively independent of each other because one is a visual anatomic assessment (*ie*, the radiograph), another is auscultatory (*ie*, rales), and the last is physiologic (*ie*, DLCO). However, even if the specificity of rales and DLCO dropped to 50% in patients in whom the chest radiograph findings were positive, the specificity would still be $> 98\%$ (*ie*, $0.93 + 0.5 \times 0.07 + 0.5 \times 0.035 = 98.25$). Therefore, an overall specificity of 98 to 99% if all three test results are normal is quite conservative. If the tests were independent, the overall sensitivity would be about 62% (*ie*, $0.9 \times 0.85 \times 0.8 = 0.62$). If there were some interdependence, it would be higher, more toward the 80% sensitivity of the presence of rales. It is reasonable to assume there is some interdependence because the same process of fibrosis leads to all three abnormalities. Therefore, a more appropriate estimate of sensitivity might be 70%.

Using these calculations, the positive predictive value if all three test results are abnormal can be determined. Using a sensitivity of 70% and specificity of 98.5% for all three tests together, if the prevalence of asbestosis were 5%, the positive predictive value when all three test results are abnormal would be about 70%. If the prevalence were 3%, the positive predictive value would be about 60%.

Although two tests could be used, the maximum sensitivity could not be greater than the lower test result value obtained (or about 80 to 85%). If the tests were somewhat independent of each other, the sensitivity would be less. If the overall sensitivity of two tests were 75%, the specificity required to give a positive predictive value of 50% can be calculated. For a prevalence of 5%, the specificity of the two combined tests must be at least 96%, and 98% if the prevalence is 3%. If there is some interdependence, then two tests may not provide this degree of specificity, while all three tests would provide it, with only a small loss of sensitivity.

Requiring the results of all three tests to be positive provides a reasonable combination of adequate sensitivity while assuring that, in the proper setting, the individual with the three positive test results, more likely than not, does have asbestosis.

Summary

Among persons in present-day asbestos-exposed cohorts, such as construction and petrochemical workers, an abnormal chest radiograph (ILO grade, 1/0 and 1/1) alone may have a positive predictive value that is too low to diagnose asbestosis with confidence. However, the diagnosis of asbestosis usually can be made on clinical grounds. Many patients will have pleural plaques. Most patients will have radiographic changes that are suggestive of diffuse interstitial pulmonary fibrosis, reduced DLCO, and rales on physical examination. In the appropriate clinical setting, only when an individual has chest radiographic findings that are compatible with asbestosis, rales, and a reduced DLCO can a clinical diagnosis of asbestosis be made with reasonable confidence.

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together in the adjudication of all claims.

[48 FR 24287, May 31, 1983]

§718.3 Scope and intent of this part.

(a) This part sets forth the standards to be applied in determining whether a coal miner is or was totally, or in the case of a claim subject to §718.306 partially, disabled due to pneumoconiosis or died due to pneumoconiosis. It also specifies the procedures and requirements to be followed in conducting medical examinations and in administering various tests relevant to such determinations.

(b) This part is designed to interpret the presumptions contained in section 411(c) of the Act, evidentiary standards and criteria contained in section 413(b) of the Act and definitional requirements and standards contained in section [illegible] of the Act within a coherent fram[illegible] for the adjudication of claim[illegible] [illegible] is intended that these enumerat[illegible] provisions of the Act be construed as provided in this part.

(c) In enacting title IV of the Act, Congress intended that claimants be given [illegible] benefit of all reasonable doub[illegible] [illegible] the existence of total or partia[illegible] [illegible]sability or death due to pneumoconiosis. This part shall be construed and applied in that spirit and is designed to reflect that intent. However, no claim shall be approved unless the record considered as a whole, in light of any applicable presumptions, provides a reasonable basis for determining that the criteria for eligibility under the Act and this part have been met.

§718.4 Definitions and use of terms.

Except as is otherwise provided by this part, the definitions and usages of terms contained in §725.101 of subpart A of part 725 of this title, as amended from time to time, shall be applicable to this part.

Subpart B—Criteria for the Development of Medical Evidence

§718.101 General.

The Office of Workers' Compensation Programs (hereinafter OWCP or the Office) shall develop the medical evidence necessary for a determination with respect to each claimant's entitlement to benefits. Each miner who files a claim for benefits under the Act shall be provided an opportunity to substantiate his or her claim by means of a complete pulmonary evaluation including, but not limited to, a chest roentgenogram (X-ray), physical examination, pulmonary function tests and a blood-gas study.

§718.102 Chest roentgenograms (X-rays).

(a) A chest roentgenogram (X-ray) shall be of suitable quality for proper classification of pneumoconiosis and shall conform to the standards for administration and interpretation of chest X-rays as described in Appendix A.

(b) A chest X-ray to establish the existence of pneumoconiosis shall be classified as Category 1, 2, 3, A, B, or C, according to the International Labour Organization Union Internationale Contra Cancer/Cincinnati (1971) International Classification of Radiographs of the Pneumoconioses (ILO-U/C 1971), or subsequent revisions thereof. A chest X-ray classified as Category Z under the ILO Classification (1958) or Short Form (1968) shall be reclassified as Category O or Category 1 as appropriate, and only the latter accepted as evidence of pneumoconiosis. A chest X-ray classified under any of the foregoing classifications as Category O, including sub-categories 0/–, 0/0, or 0/1 under the UICC/Cincinnati (1968) Classification or the ILO-U/C 1971 Classification does not constitute evidence of pneumoconiosis.

(c) A description and interpretation of the findings in terms of the classifications described in paragraph (b) of this section shall be submitted by the examining physician along with the film. The report shall specify the name and qualifications of the person who took the film and the name and qualifications of the physician interpreting the film. If the physician interpreting the film is a Board-certified or Board-eligible radiologist or a certified "B" reader (see §718.202), he or she shall so indicate. The report shall further specify that the film was interpreted in compliance with this paragraph.

(d) The original film on which the X-ray report is based shall be supplied to the Office, unless prohibited by law, in which event the report shall be considered as evidence only if the original film is otherwise available to the Office and other parties. Where the chest X-ray of a deceased miner has been lost, destroyed or is otherwise unavailable, a report of a chest X-ray submitted by any party shall be considered in connection with the claim.

(e) No chest X-ray shall constitute evidence of the presence or absence of pneumoconiosis unless it is in substantial compliance with the requirements of this section and Appendix A, except that in the case of a deceased miner where the only available X-ray is of sufficient quality for determining the presence or absence of pneumoconiosis and such X-ray was interpreted by a Board-certified or Board-eligible radiologist or a certified "B" reader (see §718.208) such X-ray shall be considered and shall be accorded such weight and probative value as is appropriate in light of all of the evidence applicable to the individual case. It shall be presumed, in the absence of evidence to the contrary, that the requirements of Appendix A have been met.

(Approved by the Office of Management and Budget under control number 1215-0090)

(Pub. L. No. 96-511)

[45 FR 13678, Feb. 29, 1980, as amended at 48 FR 24287, May 31, 1983; 49 FR 18295, Apr. 30, 1984]

§718.103 Pulmonary function tests.

(a) Any report of pulmonary function tests submitted in connection with a claim for benefits shall record the results of the forced expiratory volume in one second (FEV_1) and either the forced vital capacity (FVC) or the maximum voluntary ventilation (MVV) or both. If the MVV is reported, the results of such test shall be obtained independently rather than calculated from the results of the FEV_1. Such tests shall be administered and reported in accordance with the standards for the administration and interpretation of pulmonary function tests as described in Appendix B. It shall be presumed, in the absence of evidence to the contrary, that these requirements have been met.

(b) All pulmonary function test results submitted in connection with a claim for benefits shall be accompained by three tracings of each test performed, unless the results of two tracings of the MVV are within 5% of each other, in which case two tracings for that test shall be sufficient. Pulmonary function test results submitted in connection with a claim for benefits shall also include a statement signed by the physician or technician conducting the test setting forth the following:

(1) Date and time of test;

(2) Name, DOL claim number, age, height, and weight of claimant at the time of the test;

(3) Name of technician;

(4) Name and signature of physician supervising the test;

(5) Claimant's ability to understand the instructions, ability to follow directions and degree of cooperation in performing the tests. If the claimant is unable to complete the test, the person executing the report shall set forth the reasons for such failure;

(6) Paper speed of the instrument used;

(7) Name of the instrument used;

(8) Whether a bronchodilator was administered. If a bronchodilator is administered, the physician's report must detail values obtained both before and after administration of the bronchodilator and explain the significance of the results obtained; and

(9) That the requirements of paragraphs (b) and (c) of this section have been complied with.

(c) No results of pulmonary function tests shall constitute evidence of a respiratory or pulmonary impairment unless such tests are conducted and reported in substantial compliance with this section and Appendix B. Special consideration shall be given in the case of a deceased miner where, in the opinion of the adjudication officer, the only available tests demonstrate technically valid results obtained with good cooperation of the miner.

(The information collection requirements contained in paragraph (b) were approved by the Office of Management and Budget under control number 1215-0090)

(Pub. L. No. 96-511)

[45 FR 13678, Feb. 29, 1980, as amended at 49 FR 18295, Apr. 30, 1984]

§718.104 Report of physical examinations.

A report of any physical examination conducted in connection with a claim shall include the miner's medical and employment history. A medical report form supplied by the Office or a report containing substantially the same information shall be completed for all findings. In addition to the chest X-ray and pulmonary function tests, the physician shall use his or her judgment in the selection of other procedures such as electrocardiogram, blood-gas studies, and other blood analyses in his or her evaluation of the miner. All manifestations of chronic respiratory disease shall be noted. Any pertinent findings not specifically listed on the form shall be added by the examining physician. If heart disease secondary to lung disease is found, all symptoms and significant findings shall be noted.

(Approved by the Office of Management and Budget under control number 1215-0090)

(Pub. L. No. 96-511)

[45 FR 13678, Feb. 29, 1980, as amended at 49 FR 18295, Apr. 30, 1984]

§718.105 Arterial blood-gas studies.

(a) Blood-gas studies are performed to detect an impairment in the process of alveolar gas exchange. This defect will manifest itself primarily as a fall in arterial oxygen tension either at rest or during exercise. No blood-gas study shall be performed if medically contraindicated.

(b) A blood-gas study shall initially be administered at rest and in a sitting position. If the results of the blood-gas test at rest do not satisfy the requirements of Appendix C, an exercise blood-

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chest films or views shall be obtained if they are necessary for clarification and classification. The film and cassette shall be capable of being positioned both vertically and horizontally so that the chest roentgenogram will include both apices and costophrenic angles. If a miner is too large to permit the above requirements, then a projection with minimum loss of costophrenic angle shall be made.

(2) Miners shall be disrobed from the waist up at the time the roentgenogram is given. The facility shall provide a dressing area and, for those miners who wish to use one, the facility shall provide a clean gown. Facilities shall be heated to a comfortable temperature.

(3) Roentgenograms shall be made only with a diagnostic X-ray machine having a rotating anode tube with a maximum of a 2 mm source (focal spot).

(4) Except as provided in paragraph (5), roentgenograms shall be made with units having generators which comply with the following: (a) the generators of existing roentgenographic units acquired by the examining facility prior to July 27, 1973, shall have a minimum rating of 200 mA at 100 kVp; (b) generators of units acquired subsequent to that date shall have a minimum rating of 300 mA at 125 kVp.

NOTE: A generator with a rating of 150 kVp is recommended.

(5) Roentgenograms made with battery-powered mobile or portable equipment shall be made with units having a minimum rating of 100 mA at 110 kVp at 500 Hz, or 200 mA at 110 kVp at 60 Hz.

(6) Capacitor discharge, and field emission units may be used.

(7) Roentgenograms shall be given only with equipment having a beam-limiting device which does not cause large unexposed boundaries. The use of such a device shall be discernible from an examination of the roentgenogram.

(8) To insure high quality chest roentgenograms:

(i) The maximum exposure time shall not exceed 1/20 of a second except that with single phase units with a rating less than 300 mA at 125 kVp and subjects with chest over 28 cm postero-anterior, the exposure may be increased to not more than 1/10 of a second;

(ii) The source or focal spot to film distance shall be at least 6 feet;

(iii) Only medium-speed film and medium-speed intensifying screens shall be used;

(iv) Film-screen contact shall be maintained and verified at 6-month or shorter intervals;

(v) Intensifying screens shall be inspected at least once a month and cleaned when necessary by the method recommended by the manufacturer;

(vi) All intensifying screens in a cassette shall be of the same type and made by the same manufacturer;

(vii) When using over 90 kV, a suitable grid or other means of reducing scattered radiation shall be used;

(viii) The geometry of the radiographic system shall insure that the central axis (ray) of the primary beam is perpendicular to the plane of the film surface and impinges on the center of the film.

(9) Radiographic processing:

(i) Either automatic or manual film processing is acceptable. A constant time-temperature technique shall be meticulously employed for manual processing.

(ii) If mineral or other impurities in the processing water introduce difficulty in obtaining a high-quality roentgenogram, a suitable filter or purification system shall be used.

(10) Before the miner is advised that the examination is concluded, the roentgenogram shall be processed and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard roentgenogram, another shall be made immediately.

(11) An electric power supply shall be used which complies with the voltage, current, and regulation specified by the manufacturer of the machine.

(12) A densitometric test object may be required on each roentgenogram for an objective evaluation of film quality at the discretion of the Department of Labor.

(13) Each roentgenogram made hereunder shall be permanently and legibly marked with the name and address of the facility at which it is made, the miner's DOL claim number, the date of the roentgenogram, and left and right side of film. No other identifying markings shall be recorded on the roentgenogram.

APPENDIX B TO PART 718—STANDARDS FOR ADMINISTRATION AND INTERPRETATION OF PULMONARY FUNCTION TESTS. TABLES B1, B2, B3, B4, B5, B6

The following standards are established in accordance with section 402(f)(1)(D) of the Act. They were developed in consultation with the National Institute for Occupational Safety and Health (NIOSH). These standards are promulgated for the guidance of physicians and medical technicians to insure that uniform procedures are used in administering and interpreting ventilatory function tests and that the best available medical evidence will be submitted in support of a claim for black lung benefits. If it is established that one or more standards have not been met, the claims adjudicator may consider such fact in determining the evidentiary weight to be given to the results of the ventilatory function tests.

(1) Instruments to be used for the administration of pulmonary function tests shall be approved by NIOSH and shall conform to the following criteria:

(i) The instrument shall be accurate within ±50 ml or within ±3 percent of reading, whichever is greater.

(ii) The instrument shall be capable of measuring vital capacity from 0 to 7 liters BTPS.

(iii) The instrument shall have a low inertia and offer low resistance to airflow such that the resistance to airflow at 12 liters per second must be less than 1.5 cm H_2O/liter/sec.

(iv) The zero time point for the purpose of timing the FEV_1 shall be determined by extrapolating the steepest portion of the volume-time curve back to the maximal inspiration volume or by an equivalent method.

(v) Instruments incorporating measurements of airflow to determine volume shall conform to the same volume accuracy stated in subparagraph (1)(i) of this Appendix B when presented with flow rates from at least 0 to 12 liters per second.

(vi) The instrument or user of the instrument must have a means of correcting volumes to body temperature saturated with water vapor (BTPS) under conditions of varying ambient spirometer temperatures and barometric pressures.

(vii) The instrument used shall provide a tracing of either flow versus volume or volume versus time during the entire forced expiration and volume versus time during the MVV maneuver. A tracing is necessary to determine whether the patient has performed the test properly. The tracing must be of sufficient size that hand measurements may be made within the requirement of subparagraph (1)(i) of this Appendix B. If a paper record is made it must have a paper speed of at least 2 cm/sec and a volume sensitivity of at least 10.0 mm of chart per liter of volume. The recorder tracing must display the entire FVC maneuver at a constant speed for at least 10 seconds after the onset of exhalation. This constant speed must be reached prior to the onset of exhalation.

(viii) The instrument shall be capable of accumulating volume for a minimum of 10 seconds after the onset of exhalation.

(ix) The forced expiratory volume in 1 sec (FEV_1) measurement shall comply with the accuracy requirements stated in subparagraph (1)(i) of this Appendix B. That is, they shall be accurately measured to within ±50 ml or with ±3 percent of reading, whichever is greater.

(x) The instrument must be capable of being calibrated in the field with respect to the FEV_1. This calibration of the FEV_1 may be done either directly or indirectly through volume and time base measurements. The volume calibration source shall provide a volume displacement of at least 3 liters and shall be accurate to within ±30 ml.

(xi) For measuring maximum voluntary ventilation (MVV) the instrument shall have a response which is flat within ±10 percent up to 4 Hz at flow rates up to 12 liters per second over the volume range. The time for exhaled volume integration or recording shall be no less than 12 sec. and no more than 15 sec. The indicated time shall be accurate to within ±3 percent.

A recording of the spirometer tracing is required, and the volume sensitivity shall be such that 10 mm or more deflection corresponds to 1 liter volume.

(2) The administration of pulmonary function tests shall conform to the following criteria:

(i) Tests shall not be performed during or soon after an acute respiratory illness.

(ii) For the FEV_1 and FVC, use of a nose clip is required. The procedures shall be explained in simple terms to the patient who shall be instructed to loosen any tight clothing and stand in front of the apparatus. The subject may sit, or stand, but care should be taken on repeat testing that the same position be used. Particular attention shall be given to insure that the chin is slightly elevated with the neck slightly extended. The patient shall be instructed to make a full inspiration, either from the spirometer or the open atmosphere, using a normal breathing pattern and then blow into the apparatus, without interruption, as hard, fast, and completely as possible. At least three forced expirations shall be carried out. During the maneuvers, the patient shall be observed for compliance with instructions. The expirations shall be checked visually for reproducibility from the flow-volume or volume-time tracings. The effort shall be judged unacceptable when the patient:

(A) Has not reached full inspiration preceding the forced expiration; or

(B) Has not used maximal effort during the entire forced expiration; or

(C) Has not continued the expiration for least 5 sec. or until an obvious plateau in the volume-time curve has occurred; or

(D) Has coughed or closed his glottis; or

(E) Has an obstructed mouthpiece or a leak around the mouthpiece (obstruction due to tongue being placed in front of mouthpiece, false teeth falling in front of mouthpiece, etc.); or

(F) Has an unsatisfactory start of expiration, one characterized by excessive hesitation (or false starts), and therefore not allowing back extrapolation of time 0 (extrapolated volume on the volume-time tracing must be less than 10 percent of the FVC); or

(G) Has an excessive variability between the three acceptable curves. The variation between the two largest FEV_1's of the three acceptable tracings should not exceed 5 per-

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excessive variability between eptable curves. The variation wo largest FEV_1's of the three acings should not exceed 5 per-

cent of the largest FEV_1 or 100 ml, whichever is greater.

(iii) For the MVV, the subject shall be instructed before beginning the test that he or she will be asked to breathe as deeply and as rapidly as possible for approximately 15 seconds.

The test shall be performed with the subject in the standing position, if possible. Care shall be taken on repeat testing that the same position be used. The subject shall breathe normally into the mouthpiece of the apparatus for 10 to 15 seconds to become accustomed to the system. The subject shall then be instructed to breathe as deeply and as rapidly as possible, and shall be continually encouraged during the remainder of the maneuver. Subject shall continue the maneuver for 15 seconds. At least 5 minutes of rest shall be allowed between maneuvers. At least three MVV's shall be carried out. (But see §718.103(b).) During the maneuvers the patient shall be observed for compliance with instructions. The effort shall be judged unacceptable when the patient:

(A) Has not maintained consistent effort for at least 12 to 15 seconds; or

(B) Has coughed or closed his glottis; or

(C) Has an obstructed mouthpiece or a leak around the mouthpiece (obstruction due to tongue being placed in front of mouthpiece, false teeth falling in front of mouthpiece, etc.); or

(D) Has an excessive variability between the three acceptable curves. The variation between the two largest MVV's of the three satisfactory tracings shall not exceed 10 percent.

(iv) A calibration check shall be performed on the instrument each day before use, using a volume source of at least three liters, accurate to within ±1 percent of full scale. The room air in the syringe is introduced into the spirometer once with a flow rate of approximately 0.5 liters per second (six seconds emptying time with a 3-liter syringe) and once with a higher flow rate of approximately 3.0 liters per second (one second emptying time with a 3-liter syringe). The volume measured by the spirometer shall be between 2.90 and 3.10 liters for both trials. Accuracy of the time measurement used in determining the FEV_1 shall be checked using the manufacturer's stated procedure and shall be within ±3 percent of actual. The procedure described herein shall be performed as well as any other procedures suggested by the manufacturer of the spirometer being used.

(v)(A) The first step in evaluating a spirogram for the FEV_1 shall be to determine whether or not the patient has performed the test properly or as described in (2)(ii) above. From the three satisfactory tracings, the forced expiratory volume in one second (FEV_1) shall be measured and recorded. The largest observed FEV_1 shall be used in the analysis, corrected to BPTS.

(B) Only MVV maneuvers which demonstrate consistent effort for at least 12 seconds shall be considered acceptable. The largest accumulated volume for a 12 second period corrected to BPTS and multiplied by five is to be reported as the MVV.

PREDICTION EQUATIONS FOR FEV1 MALES * 60% OF PREDICTED **

AGE (YEARS)

HEIGHT (IN)	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46
59.1	1.85	1.88	1.90	1.75	1.74	1.72	1.70	1.69	1.67	1.66	1.64	1.62	1.61	1.59	1.58	1.56	1.54	1.53	1.51	1.49	1.48	1.46	1.45	1.43	1.41
59.4	1.88	1.90	1.93	1.78	1.77	1.75	1.74	1.72	1.70	1.69	1.67	1.65	1.64	1.62	1.61	1.59	1.57	1.56	1.54	1.53	1.51	1.49	1.48	1.46	1.44
59.8	1.90	1.93	1.96	1.82	1.80	1.78	1.77	1.75	1.74	1.72	1.70	1.69	1.67	1.65	1.64	1.62	1.61	1.59	1.57	1.56	1.54	1.52	1.51	1.49	1.48
60.2	1.93	1.96	1.99	1.85	1.84	1.81	1.80	1.78	1.77	1.75	1.73	1.72	1.70	1.68	1.67	1.65	1.64	1.62	1.60	1.59	1.57	1.56	1.54	1.52	1.51
60.6	1.96	1.99	2.01	1.88	1.86	1.85	1.83	1.81	1.80	1.78	1.76	1.75	1.73	1.72	1.70	1.68	1.67	1.65	1.64	1.62	1.60	1.59	1.57	1.56	1.54
61.0	1.99	2.01	2.04	1.91	1.89	1.88	1.86	1.84	1.83	1.81	1.80	1.78	1.76	1.75	1.73	1.72	1.70	1.68	1.67	1.65	1.63	1.62	1.60	1.59	1.57
61.4	2.01	2.04	2.07	1.94	1.92	1.91	1.89	1.88	1.86	1.84	1.83	1.81	1.79	1.78	1.76	1.75	1.73	1.71	1.70	1.68	1.67	1.65	1.63	1.62	1.60
61.8	2.04	2.07	2.10	1.97	1.96	1.94	1.92	1.91	1.89	1.87	1.86	1.84	1.83	1.81	1.79	1.78	1.76	1.75	1.73	1.71	1.70	1.68	1.67	1.65	1.63
62.2	2.07	2.10	2.12	2.00	1.99	1.97	1.95	1.94	1.92	1.91	1.89	1.87	1.86	1.84	1.83	1.81	1.79	1.78	1.76	1.74	1.73	1.71	1.70	1.68	1.66
62.6	2.10	2.12	2.15	2.03	2.02	2.00	1.99	1.97	1.95	1.94	1.92	1.90	1.89	1.87	1.86	1.84	1.82	1.81	1.79	1.78	1.76	1.74	1.73	1.71	1.69
63.0	2.13	2.15	2.18	2.07	2.05	2.03	2.02	2.00	1.98	1.97	1.95	1.94	1.92	1.90	1.89	1.87	1.85	1.84	1.82	1.81	1.79	1.77	1.76	1.74	1.72
63.4	2.15	2.18	2.21	2.10	2.08	2.06	2.05	2.03	2.02	2.00	1.98	1.97	1.95	1.93	1.92	1.90	1.88	1.87	1.85	1.84	1.82	1.80	1.79	1.77	1.75
63.8	2.18	2.21	2.23	2.13	2.11	2.10	2.08	2.06	2.05	2.03	2.01	2.00	1.98	1.96	1.95	1.93	1.91	1.90	1.88	1.87	1.85	1.83	1.82	1.80	1.78
64.2	2.21	2.24	2.26	2.16	2.14	2.13	2.11	2.09	2.08	2.06	2.05	2.03	2.01	1.99	1.98	1.96	1.94	1.93	1.91	1.90	1.88	1.86	1.85	1.83	1.81
64.6	2.24	2.26	2.29	2.19	2.17	2.16	2.14	2.13	2.11	2.09	2.08	2.06	2.04	2.02	2.01	1.99	1.97	1.96	1.94	1.93	1.91	1.89	1.88	1.86	1.84
65.0	2.26	2.29	2.32	2.23	2.20	2.19	2.17	2.16	2.14	2.12	2.11	2.09	2.08	2.06	2.05	2.03	2.01	2.00	1.98	1.97	1.95	1.93	1.92	1.90	1.88
65.4	2.29	2.32	2.34	2.25	2.24	2.22	2.20	2.19	2.17	2.16	2.14	2.12	2.11	2.09	2.08	2.06	2.04	2.03	2.01	2.00	1.98	1.96	1.95	1.93	1.91
65.7	2.32	2.35	2.37	2.28	2.27	2.25	2.24	2.22	2.20	2.19	2.17	2.16	2.14	2.12	2.11	2.09	2.07	2.06	2.04	2.03	2.01	1.99	1.98	1.96	1.94
66.1	2.35	2.37	2.40	2.31	2.30	2.28	2.27	2.25	2.23	2.22	2.20	2.19	2.17	2.15	2.14	2.12	2.10	2.09	2.07	2.06	2.04	2.02	2.01	1.99	1.97
66.5	2.37	2.40	2.43	2.35	2.33	2.31	2.30	2.28	2.27	2.25	2.23	2.22	2.20	2.18	2.17	2.15	2.13	2.12	2.10	2.09	2.07	2.05	2.04	2.02	2.00
66.9	2.40	2.43	2.46	2.38	2.36	2.34	2.33	2.31	2.30	2.28	2.26	2.25	2.23	2.21	2.20	2.18	2.16	2.15	2.13	2.12	2.10	2.08	2.07	2.05	2.03
67.3	2.43	2.46	2.48	2.41	2.39	2.38	2.36	2.34	2.33	2.31	2.30	2.28	2.26	2.24	2.23	2.21	2.19	2.18	2.16	2.15	2.13	2.11	2.10	2.08	2.06
67.7	2.46	2.48	2.51	2.44	2.42	2.41	2.39	2.37	2.36	2.34	2.33	2.31	2.29	2.27	2.26	2.24	2.22	2.21	2.19	2.18	2.16	2.14	2.13	2.11	2.09
68.1	2.48	2.51	2.54	2.47	2.45	2.44	2.42	2.41	2.39	2.37	2.36	2.34	2.33	2.31	2.30	2.28	2.26	2.25	2.23	2.22	2.20	2.18	2.17	2.15	2.13
68.5	2.51	2.54	2.57	2.50	2.49	2.47	2.45	2.44	2.42	2.40	2.39	2.37	2.36	2.34	2.33	2.31	2.29	2.28	2.26	2.25	2.23	2.21	2.20	2.18	2.16
68.9	2.54	2.57	2.59	2.53	2.52	2.50	2.48	2.47	2.45	2.44	2.42	2.40	2.39	2.37	2.36	2.34	2.32	2.31	2.29	2.28	2.26	2.24	2.23	2.21	2.19
69.3	2.57	2.59	2.62	2.56	2.55	2.53	2.52	2.50	2.48	2.47	2.45	2.43	2.42	2.40	2.39	2.37	2.35	2.34	2.32	2.31	2.29	2.27	2.26	2.24	2.22
69.7	2.59	2.62	2.65	2.60	2.58	2.56	2.55	2.53	2.51	2.50	2.48	2.47	2.45	2.43	2.42	2.40	2.38	2.37	2.35	2.34	2.32	2.30	2.29	2.27	2.25
70.1	2.62	2.65	2.68	2.63	2.61	2.59	2.58	2.56	2.55	2.53	2.51	2.50	2.48	2.46	2.45	2.43	2.41	2.40	2.38	2.37	2.35	2.33	2.32	2.30	2.28
70.5	2.65	2.68	2.70	2.66	2.64	2.63	2.61	2.59	2.58	2.56	2.54	2.53	2.51	2.49	2.48	2.46	2.44	2.43	2.41	2.40	2.38	2.36	2.35	2.33	2.31
70.9	2.68	2.70	2.73	2.69	2.67	2.66	2.64	2.62	2.61	2.59	2.58	2.56	2.54	2.52	2.51	2.49	2.47	2.46	2.44	2.43	2.41	2.39	2.38	2.36	2.34
71.3	2.70	2.73	2.76	2.72	2.70	2.69	2.67	2.66	2.64	2.62	2.61	2.59	2.57	2.55	2.54	2.52	2.50	2.49	2.47	2.46	2.44	2.42	2.41	2.39	2.37
71.7	2.73	2.76	2.79	2.75	2.73	2.72	2.70	2.69	2.67	2.65	2.64	2.62	2.61	2.59	2.58	2.56	2.54	2.53	2.51	2.50	2.48	2.46	2.45	2.43	2.41
72.0	2.76	2.79	2.81	2.78	2.77	2.75	2.73	2.72	2.70	2.69	2.67	2.65	2.64	2.62	2.61	2.59	2.57	2.56	2.54	2.53	2.51	2.49	2.48	2.46	2.44
72.4	2.78	2.81	2.84	2.81	2.80	2.78	2.77	2.75	2.73	2.72	2.70	2.68	2.67	2.65	2.64	2.62	2.60	2.59	2.57	2.56	2.54	2.52	2.51	2.49	2.47
72.8	2.82	2.84	2.87	2.85	2.83	2.81	2.80	2.78	2.76	2.75	2.73	2.72	2.70	2.68	2.67	2.65	2.63	2.62	2.60	2.59	2.57	2.55	2.54	2.52	2.50
73.2	2.84	2.87	2.90	2.88	2.86	2.84	2.83	2.81	2.80	2.78	2.76	2.75	2.73	2.71	2.70	2.68	2.66	2.65	2.63	2.62	2.60	2.58	2.57	2.55	2.53
73.6	2.87	2.90	2.92	2.91	2.89	2.88	2.86	2.84	2.83	2.81	2.79	2.78	2.76	2.74	2.73	2.71	2.69	2.68	2.66	2.65	2.63	2.61	2.60	2.58	2.56
74.0	2.90	2.93	2.95	2.94	2.92	2.91	2.89	2.87	2.86	2.84	2.83	2.81	2.79	2.77	2.76	2.74	2.72	2.71	2.69	2.68	2.66	2.64	2.63	2.61	2.59
74.4	2.93	2.95	2.98	2.97	2.95	2.94	2.92	2.91	2.89	2.87	2.86	2.84	2.82	2.80	2.79	2.77	2.75	2.74	2.72	2.71	2.69	2.67	2.66	2.64	2.62
74.8	2.95	2.98	3.01	3.00	2.99	2.97	2.95	2.94	2.92	2.90	2.89	2.87	2.86	2.84	2.83	2.81	2.79	2.78	2.76	2.75	2.73	2.71	2.70	2.68	2.66
75.2	2.98	3.01	3.03	3.03	3.02	3.00	2.98	2.97	2.95	2.94	2.92	2.90	2.89	2.87	2.86	2.84	2.82	2.81	2.79	2.78	2.76	2.74	2.73	2.71	2.69
75.6	3.01	3.04	3.06	3.06	3.05	3.03	3.02	3.00	2.98	2.97	2.95	2.93	2.92	2.90	2.89	2.87	2.85	2.84	2.82	2.81	2.79	2.77	2.76	2.74	2.72
76.0	3.04	3.06	3.09	3.09	3.08	3.06	3.05	3.03	3.01	3.00	2.98	2.97	2.95	2.93	2.92	2.90	2.88	2.87	2.85	2.84	2.82	2.80	2.79	2.77	2.75
76.4	3.06	3.09	3.12	3.13	3.11	3.09	3.08	3.06	3.05	3.03	3.01	3.00	2.98	2.96	2.95	2.93	2.91	2.90	2.88	2.87	2.85	2.83	2.82	2.80	2.78
76.8	3.09	3.12	3.15	3.16	3.14	3.12	3.11	3.09	3.08	3.06	3.04	3.03	3.01	2.99	2.98	2.96	2.94	2.93	2.91	2.90	2.88	2.86	2.85	2.83	2.81
77.2	3.12	3.15	3.17	3.19	3.17	3.16	3.14	3.12	3.11	3.09	3.08	3.06	3.04	3.02	3.01	2.99	2.97	2.96	2.94	2.93	2.91	2.89	2.88	2.86	2.84
77.6	3.14	3.17	3.20	3.22	3.20	3.19	3.17	3.15	3.14	3.12	3.11	3.09	3.07	3.05	3.04	3.02	3.00	2.99	2.97	2.96	2.94	2.92	2.91	2.89	2.87
78.0	3.17	3.20	3.23	3.25	3.23	3.22	3.20	3.19	3.17	3.15	3.14	3.12	3.10	3.08	3.07	3.05	3.03	3.02	3.00	2.99	2.97	2.95	2.94	2.92	2.90
78.3	3.20	3.23	3.26	3.28	3.27	3.25	3.23	3.22	3.20	3.18	3.17	3.15	3.14	3.12	3.11	3.09	3.07	3.06	3.04	3.03	3.01	2.99	2.98	2.96	2.94
78.7	3.23	3.26	3.28	3.31	3.30	3.28	3.26	3.25	3.23	3.22	3.20	3.18	3.17	3.15	3.14	3.12	3.10	3.09	3.07	3.06	3.04	3.02	3.01	2.99	2.97
79.1	3.26	3.28	3.31	3.34	3.33	3.31	3.30	3.28	3.26	3.25	3.23	3.21	3.20	3.18	3.17	3.15	3.13	3.12	3.10	3.09	3.07	3.05	3.04	3.02	3.00
79.5	3.28	3.31	3.34	3.38	3.36	3.34	3.33	3.31	3.29	3.28	3.26	3.25	3.23	3.21	3.20	3.18	3.16	3.15	3.13	3.12	3.10	3.08	3.07	3.05	3.03
79.9	3.31	3.34	3.37	3.41	3.39	3.37	3.36	3.34	3.33	3.31	3.29	3.28	3.26	3.24	3.23	3.21	3.19	3.18	3.16	3.15	3.13	3.11	3.10	3.08	3.06
80.3	3.34	3.37	3.39	3.44	3.42	3.41	3.39	3.37	3.36	3.34	3.32	3.31	3.29	3.27	3.26	3.24	3.22	3.21	3.19	3.18	3.16	3.14	3.13	3.11	3.09
80.7	3.37	3.39	3.42	3.47	3.45	3.44	3.42	3.40	3.39	3.37	3.36	3.34	3.32	3.30	3.29	3.27	3.25	3.24	3.22	3.21	3.19	3.17	3.16	3.14	3.12
81.1	3.39	3.42	3.45	3.50	3.48	3.47	3.45	3.44	3.42	3.40	3.39	3.37	3.35	3.33	3.32	3.30	3.28	3.27	3.25	3.24	3.22	3.20	3.19	3.17	3.15
81.5	3.42	3.45	3.48	3.53	3.52	3.50	3.48	3.47	3.45	3.43	3.42	3.40	3.39	3.37	3.36	3.34	3.32	3.31	3.29	3.28	3.26	3.24	3.23	3.21	3.19
81.9	3.45	3.48	3.50	3.56	3.55	3.53	3.51	3.50	3.48	3.47	3.45	3.43	3.42	3.40	3.39	3.37	3.35	3.34	3.32	3.31	3.29	3.27	3.26	3.24	3.22
82.3	3.48	3.50	3.53	3.59	3.58	3.56	3.55	3.53	3.51	3.50	3.48	3.46	3.45	3.43	3.42	3.40	3.38	3.37	3.35	3.34	3.32	3.30	3.29	3.27	3.25
82.7	3.51	3.53	3.56	3.63	3.61	3.59	3.58	3.56	3.54	3.53	3.51	3.50	3.48	3.46	3.45	3.43	3.41	3.40	3.38	3.37	3.35	3.33	3.32	3.30	3.28

PREDICTION EQUATIONS FOR FEV1 MALES * 80% OF PREDICTED **

HEIGHT (in)	AGE (YEARS) 47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71
59.1	1.40	1.38	1.36	1.35	1.33	1.32	1.30	1.28	1.27	1.25	1.23	1.22	1.20	1.19	1.17	1.15	1.14	1.12	1.11	1.09	1.07	1.06	1.04	1.02	1.01
59.4	1.43	1.41	1.40	1.38	1.36	1.35	1.33	1.31	1.30	1.28	1.27	1.25	1.23	1.22	1.20	1.18	1.17	1.15	1.14	1.12	1.10	1.09	1.07	1.06	1.04
59.8	1.46	1.44	1.43	1.41	1.39	1.38	1.36	1.35	1.33	1.31	1.30	1.28	1.26	1.25	1.23	1.22	1.20	1.18	1.17	1.15	1.14	1.12	1.10	1.09	1.07
60.2	1.49	1.47	1.46	1.44	1.43	1.41	1.39	1.38	1.36	1.34	1.33	1.31	1.30	1.28	1.26	1.25	1.23	1.21	1.20	1.18	1.17	1.15	1.13	1.12	1.10
60.6	1.52	1.51	1.49	1.47	1.46	1.44	1.42	1.41	1.39	1.38	1.36	1.34	1.33	1.31	1.29	1.28	1.26	1.25	1.23	1.21	1.20	1.18	1.17	1.15	1.13
61.0	1.55	1.54	1.52	1.50	1.49	1.47	1.46	1.44	1.42	1.41	1.39	1.37	1.36	1.34	1.33	1.31	1.29	1.28	1.26	1.24	1.23	1.21	1.20	1.18	1.16
61.4	1.58	1.57	1.55	1.54	1.52	1.50	1.49	1.47	1.45	1.44	1.42	1.41	1.39	1.37	1.36	1.34	1.32	1.31	1.29	1.28	1.26	1.24	1.23	1.21	1.20
61.8	1.62	1.60	1.58	1.57	1.55	1.53	1.52	1.50	1.49	1.47	1.45	1.44	1.42	1.40	1.39	1.37	1.36	1.34	1.32	1.31	1.29	1.27	1.26	1.24	1.23
62.2	1.65	1.63	1.61	1.60	1.58	1.57	1.55	1.53	1.52	1.50	1.48	1.47	1.45	1.44	1.42	1.40	1.39	1.37	1.35	1.34	1.32	1.31	1.29	1.27	1.26
62.6	1.68	1.66	1.65	1.63	1.61	1.60	1.58	1.56	1.55	1.53	1.52	1.50	1.48	1.47	1.45	1.43	1.42	1.40	1.39	1.37	1.35	1.34	1.32	1.31	1.29
63.0	1.71	1.69	1.68	1.66	1.64	1.63	1.61	1.60	1.58	1.56	1.55	1.53	1.51	1.50	1.48	1.47	1.45	1.43	1.42	1.40	1.38	1.37	1.35	1.34	1.32
63.4	1.74	1.72	1.71	1.69	1.68	1.66	1.64	1.63	1.61	1.59	1.58	1.56	1.55	1.53	1.51	1.50	1.48	1.46	1.45	1.43	1.42	1.40	1.38	1.37	1.35
63.8	1.77	1.75	1.74	1.72	1.71	1.69	1.67	1.66	1.64	1.63	1.61	1.59	1.58	1.56	1.54	1.53	1.51	1.50	1.48	1.46	1.45	1.43	1.41	1.40	1.38
64.2	1.80	1.79	1.77	1.75	1.74	1.72	1.71	1.69	1.67	1.66	1.64	1.62	1.61	1.59	1.58	1.56	1.54	1.53	1.51	1.49	1.48	1.46	1.45	1.43	1.41
64.6	1.83	1.82	1.80	1.78	1.77	1.75	1.74	1.72	1.70	1.69	1.67	1.66	1.64	1.62	1.61	1.59	1.57	1.56	1.54	1.53	1.51	1.49	1.48	1.46	1.44
65.0	1.86	1.85	1.83	1.82	1.80	1.78	1.77	1.75	1.74	1.72	1.70	1.69	1.67	1.65	1.64	1.62	1.61	1.59	1.57	1.56	1.54	1.52	1.51	1.49	1.48
65.4	1.90	1.88	1.86	1.85	1.83	1.81	1.80	1.78	1.77	1.75	1.73	1.72	1.70	1.69	1.67	1.65	1.64	1.62	1.60	1.59	1.57	1.56	1.54	1.52	1.51
65.7	1.93	1.91	1.89	1.88	1.86	1.85	1.83	1.81	1.80	1.78	1.77	1.75	1.73	1.72	1.70	1.68	1.67	1.65	1.64	1.62	1.60	1.59	1.57	1.55	1.54
66.1	1.96	1.94	1.93	1.91	1.89	1.88	1.86	1.84	1.83	1.81	1.80	1.78	1.76	1.75	1.73	1.72	1.70	1.68	1.67	1.65	1.63	1.62	1.60	1.59	1.57
66.5	1.99	1.97	1.96	1.94	1.92	1.91	1.89	1.88	1.86	1.84	1.83	1.81	1.80	1.78	1.76	1.75	1.73	1.71	1.70	1.68	1.67	1.65	1.63	1.62	1.60
66.9	2.02	2.00	1.99	1.97	1.96	1.94	1.92	1.91	1.89	1.87	1.86	1.84	1.83	1.81	1.79	1.78	1.76	1.75	1.73	1.71	1.70	1.68	1.66	1.65	1.63
67.3	2.05	2.04	2.02	2.00	1.99	1.97	1.95	1.94	1.92	1.91	1.89	1.87	1.86	1.84	1.83	1.81	1.79	1.78	1.76	1.74	1.73	1.71	1.70	1.68	1.66
67.7	2.08	2.07	2.05	2.03	2.02	2.00	1.99	1.97	1.95	1.94	1.92	1.90	1.89	1.87	1.86	1.84	1.82	1.81	1.79	1.78	1.76	1.74	1.73	1.71	1.69
68.1	2.11	2.10	2.08	2.07	2.05	2.03	2.02	2.00	1.98	1.97	1.95	1.94	1.92	1.90	1.89	1.87	1.86	1.84	1.82	1.81	1.79	1.77	1.76	1.74	1.73
68.5	2.15	2.13	2.11	2.10	2.08	2.06	2.05	2.03	2.02	2.00	1.98	1.97	1.95	1.93	1.92	1.90	1.89	1.87	1.85	1.84	1.82	1.80	1.79	1.77	1.76
68.9	2.18	2.16	2.14	2.13	2.11	2.10	2.08	2.06	2.05	2.03	2.01	2.00	1.98	1.97	1.95	1.93	1.92	1.90	1.89	1.87	1.85	1.84	1.82	1.80	1.79
69.3	2.21	2.19	2.18	2.16	2.14	2.13	2.11	2.09	2.08	2.06	2.05	2.03	2.01	2.00	1.98	1.96	1.95	1.93	1.92	1.90	1.88	1.87	1.85	1.84	1.82
69.7	2.24	2.22	2.21	2.19	2.17	2.16	2.14	2.13	2.11	2.09	2.08	2.06	2.04	2.03	2.01	2.00	1.98	1.96	1.95	1.93	1.92	1.90	1.88	1.87	1.85
70.1	2.27	2.25	2.24	2.22	2.21	2.19	2.17	2.16	2.14	2.12	2.11	2.09	2.08	2.06	2.04	2.03	2.01	1.99	1.98	1.96	1.95	1.93	1.91	1.90	1.88
70.5	2.30	2.29	2.27	2.25	2.24	2.22	2.20	2.19	2.17	2.16	2.14	2.12	2.11	2.09	2.07	2.06	2.04	2.03	2.01	1.99	1.98	1.96	1.95	1.93	1.91
70.9	2.33	2.32	2.30	2.28	2.27	2.25	2.24	2.22	2.20	2.19	2.17	2.15	2.14	2.12	2.11	2.09	2.07	2.06	2.04	2.02	2.01	1.99	1.98	1.96	1.94
71.3	2.36	2.35	2.33	2.32	2.30	2.28	2.27	2.25	2.23	2.22	2.20	2.19	2.17	2.15	2.14	2.12	2.10	2.09	2.07	2.06	2.04	2.02	2.01	1.99	1.98
71.7	2.40	2.38	2.36	2.35	2.33	2.31	2.30	2.28	2.27	2.25	2.23	2.22	2.20	2.18	2.17	2.15	2.14	2.12	2.10	2.09	2.07	2.05	2.04	2.02	2.01
72.0	2.43	2.41	2.39	2.38	2.36	2.35	2.33	2.31	2.30	2.28	2.26	2.25	2.23	2.22	2.20	2.18	2.17	2.15	2.13	2.12	2.10	2.09	2.07	2.05	2.04
72.4	2.46	2.44	2.43	2.41	2.39	2.38	2.36	2.34	2.33	2.31	2.30	2.28	2.26	2.25	2.23	2.21	2.20	2.18	2.17	2.15	2.13	2.12	2.10	2.09	2.07
72.8	2.49	2.47	2.46	2.44	2.42	2.41	2.39	2.38	2.36	2.34	2.33	2.31	2.29	2.28	2.26	2.25	2.23	2.21	2.20	2.18	2.16	2.15	2.13	2.12	2.10
73.2	2.52	2.50	2.49	2.47	2.46	2.44	2.42	2.41	2.39	2.37	2.36	2.34	2.33	2.31	2.29	2.28	2.26	2.24	2.23	2.21	2.20	2.18	2.16	2.15	2.13
73.6	2.55	2.53	2.52	2.50	2.49	2.47	2.45	2.44	2.42	2.41	2.39	2.37	2.36	2.34	2.32	2.31	2.29	2.28	2.26	2.24	2.23	2.21	2.19	2.18	2.16
74.0	2.58	2.57	2.55	2.53	2.52	2.50	2.49	2.47	2.45	2.44	2.42	2.40	2.39	2.37	2.36	2.34	2.32	2.31	2.29	2.27	2.26	2.24	2.23	2.21	2.19
74.4	2.61	2.60	2.58	2.56	2.55	2.53	2.52	2.50	2.48	2.47	2.45	2.44	2.42	2.40	2.39	2.37	2.35	2.34	2.32	2.31	2.29	2.27	2.26	2.24	2.22
74.8	2.64	2.63	2.61	2.60	2.58	2.56	2.55	2.53	2.52	2.50	2.48	2.47	2.45	2.43	2.42	2.40	2.39	2.37	2.35	2.34	2.32	2.30	2.29	2.27	2.26
75.2	2.68	2.66	2.64	2.63	2.61	2.59	2.58	2.56	2.55	2.53	2.51	2.50	2.48	2.47	2.45	2.43	2.42	2.40	2.38	2.37	2.35	2.34	2.32	2.30	2.29
75.6	2.71	2.69	2.67	2.66	2.64	2.63	2.61	2.59	2.58	2.56	2.55	2.53	2.51	2.50	2.48	2.46	2.45	2.43	2.42	2.40	2.38	2.37	2.35	2.33	2.32
76.0	2.74	2.72	2.71	2.69	2.67	2.66	2.64	2.62	2.61	2.59	2.58	2.56	2.54	2.53	2.51	2.50	2.48	2.46	2.45	2.43	2.41	2.40	2.38	2.37	2.35
76.4	2.77	2.75	2.74	2.72	2.70	2.69	2.67	2.66	2.64	2.62	2.61	2.59	2.58	2.56	2.54	2.53	2.51	2.49	2.48	2.46	2.45	2.43	2.41	2.40	2.38
76.8	2.80	2.78	2.77	2.75	2.74	2.72	2.70	2.69	2.67	2.65	2.64	2.62	2.61	2.59	2.57	2.56	2.54	2.53	2.51	2.49	2.48	2.46	2.44	2.43	2.41
77.2	2.83	2.82	2.80	2.78	2.77	2.75	2.73	2.72	2.70	2.69	2.67	2.65	2.64	2.62	2.61	2.59	2.57	2.56	2.54	2.52	2.51	2.49	2.48	2.46	2.44
77.6	2.86	2.85	2.83	2.81	2.80	2.78	2.77	2.75	2.73	2.72	2.70	2.68	2.67	2.65	2.64	2.62	2.60	2.59	2.57	2.56	2.54	2.52	2.51	2.49	2.47
78.0	2.89	2.88	2.86	2.85	2.83	2.81	2.80	2.78	2.76	2.75	2.73	2.72	2.70	2.68	2.67	2.65	2.64	2.62	2.60	2.59	2.57	2.55	2.54	2.52	2.51
78.3	2.93	2.91	2.89	2.88	2.86	2.84	2.83	2.81	2.80	2.78	2.76	2.75	2.73	2.71	2.70	2.68	2.67	2.65	2.63	2.62	2.60	2.58	2.57	2.55	2.54
78.7	2.96	2.94	2.92	2.91	2.89	2.88	2.86	2.84	2.83	2.81	2.79	2.78	2.76	2.75	2.73	2.71	2.70	2.68	2.67	2.65	2.63	2.62	2.60	2.58	2.57
79.1	2.99	2.97	2.96	2.94	2.92	2.91	2.89	2.87	2.86	2.84	2.83	2.81	2.79	2.78	2.76	2.74	2.73	2.71	2.70	2.68	2.66	2.65	2.63	2.62	2.60
79.5	3.02	3.00	2.99	2.97	2.95	2.94	2.92	2.91	2.89	2.87	2.86	2.84	2.82	2.81	2.79	2.78	2.76	2.74	2.73	2.71	2.70	2.68	2.66	2.65	2.63
79.9	3.05	3.03	3.02	3.00	2.99	2.97	2.95	2.94	2.92	2.90	2.89	2.87	2.86	2.84	2.82	2.81	2.79	2.77	2.76	2.74	2.73	2.71	2.69	2.68	2.66
80.3	3.08	3.07	3.05	3.03	3.02	3.00	2.98	2.97	2.95	2.94	2.92	2.90	2.89	2.87	2.85	2.84	2.82	2.81	2.79	2.77	2.76	2.74	2.73	2.71	2.69
80.7	3.11	3.10	3.08	3.06	3.05	3.03	3.02	3.00	2.98	2.97	2.95	2.93	2.92	2.90	2.89	2.87	2.85	2.84	2.82	2.80	2.79	2.77	2.76	2.74	2.72
81.1	3.14	3.13	3.11	3.10	3.08	3.06	3.05	3.03	3.01	3.00	2.98	2.97	2.95	2.93	2.92	2.90	2.88	2.87	2.85	2.84	2.82	2.80	2.79	2.77	2.76
81.5	3.18	3.16	3.14	3.13	3.11	3.09	3.08	3.06	3.05	3.03	3.01	3.00	2.98	2.96	2.95	2.93	2.92	2.90	2.88	2.87	2.85	2.83	2.82	2.80	2.79
81.9	3.21	3.19	3.17	3.16	3.14	3.13	3.11	3.09	3.08	3.06	3.04	3.03	3.01	3.00	2.98	2.96	2.95	2.93	2.91	2.90	2.88	2.87	2.85	2.83	2.82
82.3	3.24	3.22	3.21	3.19	3.17	3.16	3.14	3.12	3.11	3.09	3.08	3.06	3.04	3.03	3.01	2.99	2.98	2.96	2.95	2.93	2.91	2.90	2.88	2.87	2.85
82.7	3.27	3.25	3.24	3.22	3.20	3.19	3.17	3.16	3.14	3.12	3.11	3.09	3.07	3.06	3.04	3.03	3.01	2.99	2.98	2.96	2.94	2.93	2.91	2.90	2.88

PREDICTION EQUATIONS FOR FEV1 FEMALES * 80% OF PREDICTED **

HEIGHT (IN)	AGE (YEARS) 22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46
51.2	1.35	1.34	1.33	1.31	1.30	1.29	1.28	1.26	1.25	1.24	1.23	1.21	1.20	1.19	1.18	1.16	1.15	1.14	1.13	1.11	1.10	1.09	1.08	1.06	1.05
51.6	1.37	1.36	1.34	1.33	1.32	1.31	1.29	1.28	1.27	1.26	1.24	1.23	1.22	1.21	1.19	1.18	1.17	1.16	1.14	1.13	1.12	1.11	1.09	1.08	1.07
52.0	1.38	1.37	1.36	1.35	1.33	1.32	1.31	1.30	1.28	1.27	1.26	1.25	1.23	1.22	1.21	1.20	1.18	1.17	1.16	1.15	1.13	1.12	1.11	1.10	1.08
52.4	1.40	1.39	1.38	1.36	1.35	1.34	1.33	1.31	1.30	1.29	1.28	1.26	1.25	1.24	1.23	1.21	1.20	1.19	1.18	1.16	1.15	1.14	1.13	1.11	1.10
52.8	1.42	1.40	1.39	1.38	1.37	1.35	1.34	1.33	1.32	1.30	1.29	1.28	1.27	1.25	1.24	1.23	1.22	1.20	1.19	1.18	1.17	1.15	1.14	1.13	1.12
53.1	1.43	1.42	1.41	1.40	1.38	1.37	1.36	1.35	1.33	1.32	1.31	1.30	1.28	1.27	1.26	1.25	1.23	1.22	1.21	1.20	1.18	1.17	1.16	1.15	1.13
53.5	1.45	1.44	1.42	1.41	1.40	1.39	1.37	1.36	1.35	1.34	1.32	1.31	1.30	1.29	1.27	1.26	1.25	1.24	1.22	1.21	1.20	1.19	1.17	1.16	1.15
53.9	1.47	1.45	1.44	1.43	1.42	1.40	1.39	1.38	1.37	1.35	1.34	1.33	1.32	1.30	1.29	1.28	1.27	1.25	1.24	1.23	1.22	1.20	1.19	1.18	1.17
54.3	1.48	1.47	1.46	1.44	1.43	1.42	1.41	1.39	1.38	1.37	1.36	1.34	1.33	1.32	1.31	1.29	1.28	1.27	1.26	1.24	1.23	1.22	1.21	1.19	1.18
54.7	1.50	1.49	1.47	1.46	1.45	1.44	1.42	1.41	1.40	1.39	1.37	1.36	1.35	1.34	1.32	1.31	1.30	1.29	1.27	1.26	1.25	1.24	1.22	1.21	1.20
55.1	1.51	1.50	1.49	1.48	1.46	1.45	1.44	1.43	1.41	1.40	1.39	1.38	1.36	1.35	1.34	1.33	1.31	1.30	1.29	1.28	1.26	1.25	1.24	1.23	1.21
55.5	1.53	1.52	1.51	1.49	1.48	1.47	1.46	1.44	1.43	1.42	1.41	1.39	1.38	1.37	1.36	1.34	1.33	1.32	1.31	1.29	1.28	1.27	1.26	1.24	1.23
55.9	1.55	1.53	1.52	1.51	1.50	1.48	1.47	1.46	1.45	1.43	1.42	1.41	1.40	1.38	1.37	1.36	1.35	1.33	1.32	1.31	1.30	1.28	1.27	1.26	1.25
56.3	1.56	1.55	1.54	1.53	1.51	1.50	1.49	1.48	1.46	1.45	1.44	1.43	1.41	1.40	1.39	1.38	1.36	1.35	1.34	1.33	1.31	1.30	1.29	1.28	1.26
56.7	1.58	1.57	1.55	1.54	1.53	1.52	1.50	1.49	1.48	1.47	1.45	1.44	1.43	1.42	1.40	1.39	1.38	1.37	1.35	1.34	1.33	1.32	1.30	1.29	1.28
57.1	1.60	1.58	1.57	1.56	1.55	1.53	1.52	1.51	1.50	1.48	1.47	1.46	1.45	1.43	1.42	1.41	1.40	1.38	1.37	1.36	1.35	1.33	1.32	1.31	1.30
57.5	1.61	1.60	1.59	1.57	1.56	1.55	1.54	1.52	1.51	1.50	1.49	1.47	1.46	1.45	1.44	1.42	1.41	1.40	1.39	1.37	1.36	1.35	1.34	1.32	1.31
57.9	1.63	1.62	1.60	1.59	1.58	1.57	1.55	1.54	1.53	1.52	1.50	1.49	1.48	1.47	1.45	1.44	1.43	1.42	1.40	1.39	1.38	1.37	1.35	1.34	1.33
58.3	1.64	1.63	1.62	1.61	1.59	1.58	1.57	1.56	1.54	1.53	1.52	1.51	1.49	1.48	1.47	1.46	1.44	1.43	1.42	1.41	1.39	1.38	1.37	1.36	1.34
58.7	1.66	1.65	1.64	1.62	1.61	1.60	1.59	1.57	1.56	1.55	1.54	1.52	1.51	1.50	1.49	1.47	1.46	1.45	1.44	1.42	1.41	1.40	1.39	1.37	1.36
59.1	1.68	1.66	1.65	1.64	1.63	1.61	1.60	1.59	1.58	1.56	1.55	1.54	1.53	1.51	1.50	1.49	1.48	1.46	1.45	1.44	1.43	1.41	1.40	1.39	1.38
59.4	1.69	1.68	1.67	1.65	1.64	1.63	1.62	1.60	1.59	1.58	1.57	1.55	1.54	1.53	1.52	1.50	1.49	1.48	1.47	1.45	1.44	1.43	1.42	1.40	1.39
59.8	1.71	1.70	1.68	1.67	1.66	1.65	1.63	1.62	1.61	1.60	1.58	1.57	1.56	1.55	1.53	1.52	1.51	1.50	1.48	1.47	1.46	1.45	1.43	1.42	1.41
60.2	1.72	1.71	1.70	1.69	1.67	1.66	1.65	1.64	1.62	1.61	1.60	1.59	1.57	1.56	1.55	1.54	1.52	1.51	1.50	1.49	1.47	1.46	1.45	1.44	1.42
60.6	1.74	1.73	1.72	1.70	1.69	1.68	1.67	1.65	1.64	1.63	1.62	1.60	1.59	1.58	1.57	1.55	1.54	1.53	1.52	1.50	1.49	1.48	1.47	1.45	1.44
61.0	1.76	1.74	1.73	1.72	1.71	1.69	1.68	1.67	1.66	1.64	1.63	1.62	1.61	1.59	1.58	1.57	1.56	1.54	1.53	1.52	1.51	1.49	1.48	1.47	1.46
61.4	1.77	1.76	1.75	1.74	1.72	1.71	1.70	1.69	1.67	1.66	1.65	1.64	1.62	1.61	1.60	1.59	1.57	1.56	1.55	1.54	1.52	1.51	1.50	1.49	1.47
61.8	1.79	1.78	1.76	1.75	1.74	1.73	1.71	1.70	1.69	1.68	1.66	1.65	1.64	1.63	1.61	1.60	1.59	1.58	1.56	1.55	1.54	1.53	1.51	1.50	1.49
62.2	1.81	1.79	1.78	1.77	1.76	1.74	1.73	1.72	1.71	1.69	1.68	1.67	1.66	1.64	1.63	1.62	1.61	1.59	1.58	1.57	1.56	1.54	1.53	1.52	1.51
62.6	1.82	1.81	1.80	1.78	1.77	1.76	1.75	1.73	1.72	1.71	1.70	1.68	1.67	1.66	1.65	1.63	1.62	1.61	1.60	1.58	1.57	1.56	1.55	1.53	1.52
63.0	1.84	1.83	1.81	1.80	1.79	1.78	1.76	1.75	1.74	1.73	1.71	1.70	1.69	1.68	1.66	1.65	1.64	1.63	1.61	1.60	1.59	1.58	1.56	1.55	1.54
63.4	1.85	1.84	1.83	1.82	1.80	1.79	1.78	1.77	1.75	1.74	1.73	1.72	1.70	1.69	1.68	1.67	1.65	1.64	1.63	1.62	1.60	1.59	1.58	1.57	1.55
63.8	1.87	1.86	1.85	1.83	1.82	1.81	1.80	1.78	1.77	1.76	1.75	1.73	1.72	1.71	1.70	1.68	1.67	1.66	1.65	1.63	1.62	1.61	1.60	1.58	1.57
64.2	1.89	1.87	1.86	1.85	1.84	1.82	1.81	1.80	1.79	1.77	1.76	1.75	1.74	1.72	1.71	1.70	1.69	1.67	1.66	1.65	1.64	1.62	1.61	1.60	1.59
64.6	1.90	1.89	1.88	1.87	1.85	1.84	1.83	1.82	1.80	1.79	1.78	1.77	1.75	1.74	1.73	1.72	1.70	1.69	1.68	1.67	1.65	1.64	1.63	1.62	1.60
65.0	1.92	1.91	1.89	1.88	1.87	1.86	1.84	1.83	1.82	1.81	1.79	1.78	1.77	1.76	1.74	1.73	1.72	1.71	1.69	1.68	1.67	1.66	1.64	1.63	1.62
65.4	1.94	1.92	1.91	1.90	1.89	1.87	1.86	1.85	1.84	1.82	1.81	1.80	1.79	1.77	1.76	1.75	1.74	1.72	1.71	1.70	1.69	1.67	1.66	1.65	1.64
65.7	1.95	1.94	1.93	1.91	1.90	1.89	1.88	1.86	1.85	1.84	1.83	1.81	1.80	1.79	1.78	1.76	1.75	1.74	1.73	1.71	1.70	1.69	1.68	1.66	1.65
66.1	1.97	1.96	1.94	1.93	1.92	1.91	1.89	1.88	1.87	1.86	1.84	1.83	1.82	1.81	1.79	1.78	1.77	1.76	1.74	1.73	1.72	1.71	1.69	1.68	1.67
66.5	1.98	1.97	1.96	1.95	1.93	1.92	1.91	1.90	1.88	1.87	1.86	1.85	1.83	1.82	1.81	1.80	1.78	1.77	1.76	1.75	1.73	1.72	1.71	1.70	1.68
66.9	2.00	1.99	1.98	1.96	1.95	1.94	1.93	1.91	1.90	1.89	1.88	1.86	1.85	1.84	1.83	1.81	1.80	1.79	1.78	1.76	1.75	1.74	1.73	1.71	1.70
67.3	2.02	2.00	1.99	1.98	1.97	1.95	1.94	1.93	1.92	1.90	1.89	1.88	1.87	1.85	1.84	1.83	1.82	1.80	1.79	1.78	1.77	1.75	1.74	1.73	1.72
67.7	2.03	2.02	2.01	2.00	1.98	1.97	1.96	1.95	1.93	1.92	1.91	1.90	1.88	1.87	1.86	1.85	1.83	1.82	1.81	1.80	1.78	1.77	1.76	1.75	1.73
68.1	2.05	2.04	2.02	2.01	2.00	1.99	1.97	1.96	1.95	1.94	1.92	1.91	1.90	1.89	1.87	1.86	1.85	1.84	1.82	1.81	1.80	1.79	1.77	1.76	1.75
68.5	2.07	2.05	2.04	2.03	2.02	2.00	1.99	1.98	1.97	1.95	1.94	1.93	1.92	1.90	1.89	1.88	1.87	1.85	1.84	1.83	1.82	1.80	1.79	1.78	1.77
68.9	2.08	2.07	2.06	2.04	2.03	2.02	2.01	1.99	1.98	1.97	1.96	1.94	1.93	1.92	1.91	1.89	1.88	1.87	1.86	1.84	1.83	1.82	1.81	1.79	1.78
69.3	2.10	2.08	2.07	2.06	2.05	2.03	2.02	2.01	2.00	1.98	1.97	1.96	1.95	1.93	1.92	1.91	1.90	1.88	1.87	1.86	1.85	1.83	1.82	1.81	1.80
69.7	2.11	2.10	2.09	2.08	2.06	2.05	2.04	2.03	2.01	2.00	1.99	1.98	1.96	1.95	1.94	1.93	1.91	1.90	1.89	1.88	1.86	1.85	1.84	1.83	1.81
70.1	2.13	2.12	2.10	2.09	2.08	2.07	2.05	2.04	2.03	2.02	2.00	1.99	1.98	1.97	1.95	1.94	1.93	1.92	1.90	1.89	1.88	1.87	1.85	1.84	1.83
70.5	2.15	2.13	2.12	2.11	2.10	2.08	2.07	2.06	2.05	2.03	2.02	2.01	2.00	1.98	1.97	1.96	1.95	1.93	1.92	1.91	1.90	1.88	1.87	1.86	1.85
70.9	2.16	2.15	2.14	2.12	2.11	2.10	2.09	2.07	2.06	2.05	2.04	2.02	2.01	2.00	1.99	1.97	1.96	1.95	1.94	1.92	1.91	1.90	1.89	1.87	1.86
71.3	2.18	2.17	2.15	2.14	2.13	2.12	2.10	2.09	2.08	2.07	2.05	2.04	2.03	2.02	2.00	1.99	1.98	1.97	1.95	1.94	1.93	1.92	1.90	1.89	1.88
71.7	2.19	2.18	2.17	2.16	2.14	2.13	2.12	2.11	2.09	2.08	2.07	2.06	2.04	2.03	2.02	2.01	1.99	1.98	1.97	1.96	1.94	1.93	1.92	1.91	1.89
72.0	2.21	2.20	2.19	2.17	2.16	2.15	2.14	2.12	2.11	2.10	2.09	2.07	2.06	2.05	2.04	2.02	2.01	2.00	1.99	1.97	1.96	1.95	1.94	1.92	1.91
72.4	2.23	2.21	2.20	2.19	2.18	2.16	2.15	2.14	2.13	2.11	2.10	2.09	2.08	2.06	2.05	2.04	2.03	2.01	2.00	1.99	1.98	1.96	1.95	1.94	1.93
72.8	2.24	2.23	2.22	2.21	2.19	2.18	2.17	2.16	2.14	2.13	2.12	2.11	2.09	2.08	2.07	2.06	2.04	2.03	2.02	2.01	1.99	1.98	1.97	1.96	1.94
73.2	2.26	2.25	2.23	2.22	2.21	2.20	2.18	2.17	2.16	2.15	2.13	2.12	2.11	2.10	2.08	2.07	2.06	2.05	2.03	2.02	2.01	2.00	1.98	1.97	1.96
73.6	2.28	2.26	2.25	2.24	2.23	2.21	2.20	2.19	2.18	2.16	2.15	2.14	2.13	2.11	2.10	2.09	2.08	2.06	2.05	2.04	2.03	2.01	2.00	1.99	1.98
74.0	2.29	2.28	2.27	2.25	2.24	2.23	2.22	2.20	2.19	2.18	2.17	2.15	2.14	2.13	2.12	2.10	2.09	2.08	2.07	2.05	2.04	2.03	2.02	2.00	1.99
74.4	2.31	2.30	2.28	2.27	2.26	2.25	2.23	2.22	2.21	2.20	2.18	2.17	2.16	2.15	2.13	2.12	2.11	2.10	2.08	2.07	2.06	2.05	2.03	2.02	2.01
74.8	2.32	2.31	2.30	2.29	2.27	2.26	2.25	2.24	2.22	2.21	2.20	2.19	2.17	2.16	2.15	2.14	2.12	2.11	2.10	2.09	2.07	2.06	2.05	2.04	2.02

PREDICTION EQUATIONS FOR FEV1 FEMALES [illegible] OUT OF PREDICTED [illegible]

HEIGHT (IN)	AGE (YEARS) 47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71
51.2	1.04	1.02	1.01	1.00	0.99	0.97	0.96	0.95	0.94	0.92	0.91	0.90	0.89	0.87	0.86	0.85	0.84	0.82	0.81	0.80	0.79	0.77	0.76	0.75	0.73
51.6	1.05	1.04	1.03	1.02	1.00	0.99	0.98	0.97	0.95	0.94	0.93	0.92	0.90	0.89	0.88	0.86	0.85	0.84	0.83	0.81	0.80	0.79	0.78	0.76	0.75
52.0	1.07	1.06	1.04	1.03	1.02	1.01	0.99	0.98	0.97	0.96	0.94	0.93	0.92	0.91	0.89	0.88	0.87	0.86	0.84	0.83	0.82	0.81	0.79	0.78	0.77
52.4	1.09	1.07	1.06	1.05	1.04	1.02	1.01	1.00	0.99	0.97	0.96	0.95	0.93	0.92	0.91	0.90	0.88	0.87	0.86	0.85	0.83	0.82	0.81	0.80	0.78
52.8	1.10	1.09	1.08	1.06	1.05	1.04	1.03	1.01	1.00	0.99	0.98	0.96	0.95	0.94	0.93	0.91	0.90	0.89	0.88	0.86	0.85	0.84	0.83	0.81	0.80
53.1	1.12	1.11	1.09	1.08	1.07	1.06	1.04	1.03	1.02	1.00	0.99	0.98	0.97	0.95	0.94	0.93	0.92	0.90	0.89	0.88	0.87	0.85	0.84	0.83	0.82
53.5	1.13	1.12	1.11	1.10	1.08	1.07	1.06	1.05	1.03	1.02	1.01	1.00	0.98	0.97	0.96	0.95	0.93	0.92	0.91	0.90	0.89	0.87	0.86	0.84	0.83
53.9	1.15	1.14	1.13	1.11	1.10	1.09	1.08	1.06	1.05	1.04	1.02	1.01	1.00	0.99	0.97	0.96	0.95	0.94	0.93	0.91	0.90	0.89	0.87	0.86	0.85
54.3	1.17	1.15	1.14	1.13	1.12	1.10	1.09	1.08	1.07	1.05	1.04	1.03	1.02	1.00	0.99	0.98	0.97	0.95	0.94	0.93	0.92	0.90	0.89	0.88	0.86
54.7	1.18	1.17	1.16	1.15	1.13	1.12	1.11	1.10	1.08	1.07	1.06	1.04	1.03	1.02	1.01	0.99	0.98	0.97	0.96	0.94	0.93	0.92	0.91	0.89	0.88
55.1	1.20	1.19	1.17	1.16	1.15	1.14	1.12	1.11	1.10	1.09	1.07	1.06	1.05	1.04	1.02	1.01	1.00	0.99	0.97	0.96	0.95	0.93	0.92	0.91	0.90
55.5	1.22	1.20	1.19	1.18	1.17	1.15	1.14	1.13	1.11	1.10	1.09	1.08	1.06	1.05	1.04	1.03	1.01	1.00	0.99	0.98	0.96	0.95	0.94	0.93	0.91
55.9	1.23	1.22	1.21	1.19	1.18	1.17	1.16	1.14	1.13	1.12	1.11	1.09	1.08	1.07	1.06	1.04	1.03	1.02	1.00	0.99	0.98	0.97	0.95	0.94	0.93
56.3	1.25	1.24	1.22	1.21	1.20	1.19	1.17	1.16	1.15	1.13	1.12	1.11	1.10	1.08	1.07	1.06	1.05	1.03	1.02	1.01	1.00	0.98	0.97	0.96	0.95
56.7	1.26	1.25	1.24	1.23	1.21	1.20	1.19	1.18	1.16	1.15	1.14	1.13	1.11	1.10	1.09	1.08	1.06	1.05	1.04	1.03	1.01	1.00	0.99	0.97	0.96
57.1	1.28	1.27	1.26	1.24	1.23	1.22	1.20	1.19	1.18	1.17	1.15	1.14	1.13	1.12	1.10	1.09	1.08	1.07	1.05	1.04	1.03	1.02	1.00	0.99	0.98
57.5	1.30	1.28	1.27	1.26	1.25	1.23	1.22	1.21	1.20	1.18	1.17	1.16	1.15	1.13	1.12	1.11	1.10	1.08	1.07	1.06	1.04	1.03	1.02	1.01	0.99
57.9	1.31	1.30	1.29	1.28	1.26	1.25	1.24	1.22	1.21	1.20	1.19	1.17	1.16	1.15	1.14	1.12	1.11	1.10	1.09	1.07	1.06	1.05	1.04	1.02	1.01
58.3	1.33	1.32	1.30	1.29	1.28	1.27	1.25	1.24	1.23	1.22	1.20	1.19	1.18	1.17	1.15	1.14	1.13	1.12	1.10	1.09	1.08	1.06	1.05	1.04	1.03
58.7	1.35	1.33	1.32	1.31	1.29	1.28	1.27	1.26	1.24	1.23	1.22	1.21	1.19	1.18	1.17	1.16	1.14	1.13	1.12	1.11	1.09	1.08	1.07	1.06	1.04
59.1	1.36	1.35	1.34	1.32	1.31	1.30	1.29	1.27	1.26	1.25	1.24	1.22	1.21	1.20	1.19	1.17	1.16	1.15	1.13	1.12	1.11	1.10	1.08	1.07	1.06
59.4	1.38	1.37	1.35	1.34	1.33	1.31	1.30	1.29	1.28	1.26	1.25	1.24	1.23	1.21	1.20	1.19	1.18	1.16	1.15	1.14	1.13	1.11	1.10	1.09	1.08
59.8	1.39	1.38	1.37	1.36	1.34	1.33	1.32	1.31	1.29	1.28	1.27	1.26	1.24	1.23	1.22	1.20	1.19	1.18	1.17	1.15	1.14	1.13	1.12	1.10	1.09
60.2	1.41	1.40	1.38	1.37	1.36	1.35	1.33	1.32	1.31	1.30	1.28	1.27	1.26	1.25	1.23	1.22	1.21	1.20	1.18	1.17	1.16	1.15	1.13	1.12	1.11
60.6	1.43	1.41	1.40	1.39	1.38	1.36	1.35	1.34	1.33	1.31	1.30	1.29	1.28	1.26	1.25	1.24	1.22	1.21	1.20	1.19	1.17	1.16	1.15	1.14	1.12
61.0	1.44	1.43	1.42	1.40	1.39	1.38	1.37	1.35	1.34	1.33	1.32	1.30	1.29	1.28	1.27	1.25	1.24	1.23	1.22	1.20	1.19	1.18	1.17	1.15	1.14
61.4	1.46	1.45	1.43	1.42	1.41	1.40	1.38	1.37	1.36	1.35	1.33	1.32	1.31	1.29	1.28	1.27	1.26	1.24	1.23	1.22	1.21	1.19	1.18	1.17	1.16
61.8	1.47	1.46	1.45	1.44	1.42	1.41	1.40	1.39	1.37	1.36	1.35	1.34	1.32	1.31	1.30	1.29	1.27	1.26	1.25	1.23	1.22	1.21	1.20	1.19	1.17
62.2	1.49	1.48	1.47	1.45	1.44	1.43	1.42	1.40	1.39	1.38	1.37	1.35	1.34	1.33	1.32	1.30	1.29	1.28	1.26	1.25	1.24	1.23	1.21	1.20	1.19
62.6	1.51	1.49	1.48	1.47	1.46	1.45	1.43	1.42	1.41	1.39	1.38	1.37	1.36	1.34	1.33	1.32	1.31	1.29	1.28	1.27	1.25	1.24	1.23	1.22	1.20
63.0	1.52	1.51	1.50	1.49	1.47	1.46	1.45	1.44	1.42	1.41	1.40	1.39	1.37	1.36	1.35	1.33	1.32	1.31	1.30	1.28	1.27	1.26	1.25	1.23	1.22
63.4	1.54	1.53	1.51	1.50	1.49	1.48	1.46	1.45	1.44	1.43	1.41	1.40	1.39	1.38	1.36	1.35	1.34	1.33	1.31	1.30	1.29	1.28	1.26	1.25	1.24
63.8	1.56	1.54	1.53	1.52	1.51	1.49	1.48	1.47	1.46	1.44	1.43	1.42	1.40	1.39	1.38	1.37	1.35	1.34	1.33	1.32	1.30	1.29	1.28	1.27	1.25
64.2	1.57	1.56	1.55	1.53	1.52	1.51	1.50	1.48	1.47	1.46	1.45	1.43	1.42	1.41	1.40	1.38	1.37	1.36	1.35	1.33	1.32	1.31	1.29	1.28	1.27
64.6	1.59	1.58	1.56	1.55	1.54	1.53	1.51	1.50	1.49	1.47	1.46	1.45	1.44	1.42	1.41	1.40	1.39	1.38	1.36	1.35	1.34	1.32	1.31	1.30	1.29
65.0	1.60	1.59	1.58	1.57	1.55	1.54	1.53	1.52	1.50	1.49	1.48	1.47	1.45	1.44	1.43	1.41	1.40	1.39	1.38	1.37	1.35	1.34	1.33	1.31	1.30
65.4	1.62	1.61	1.60	1.58	1.57	1.56	1.55	1.53	1.52	1.51	1.49	1.48	1.47	1.46	1.44	1.43	1.42	1.41	1.39	1.38	1.37	1.36	1.34	1.33	1.32
65.7	1.64	1.62	1.61	1.60	1.59	1.57	1.56	1.55	1.54	1.52	1.51	1.50	1.49	1.47	1.46	1.45	1.44	1.42	1.41	1.40	1.38	1.37	1.36	1.35	1.33
66.1	1.65	1.64	1.63	1.62	1.60	1.59	1.58	1.56	1.55	1.54	1.53	1.51	1.50	1.49	1.48	1.46	1.45	1.44	1.43	1.41	1.40	1.39	1.38	1.36	1.35
66.5	1.67	1.66	1.64	1.63	1.62	1.61	1.59	1.58	1.57	1.56	1.54	1.53	1.52	1.51	1.49	1.48	1.47	1.46	1.44	1.43	1.42	1.40	1.39	1.38	1.37
66.9	1.69	1.67	1.66	1.65	1.64	1.62	1.61	1.60	1.58	1.57	1.56	1.55	1.53	1.52	1.51	1.50	1.48	1.47	1.46	1.45	1.43	1.42	1.41	1.40	1.38
67.3	1.70	1.69	1.68	1.66	1.65	1.64	1.63	1.61	1.60	1.59	1.58	1.56	1.55	1.54	1.53	1.51	1.50	1.49	1.48	1.46	1.45	1.44	1.42	1.41	1.40
67.7	1.72	1.71	1.69	1.68	1.67	1.65	1.64	1.63	1.62	1.60	1.59	1.58	1.57	1.55	1.54	1.53	1.52	1.50	1.49	1.48	1.46	1.45	1.44	1.43	1.42
68.1	1.73	1.72	1.71	1.70	1.68	1.67	1.66	1.65	1.63	1.62	1.61	1.60	1.58	1.57	1.56	1.55	1.53	1.52	1.51	1.49	1.48	1.47	1.46	1.44	1.43
68.5	1.75	1.74	1.73	1.71	1.70	1.69	1.67	1.66	1.65	1.64	1.62	1.61	1.60	1.59	1.57	1.56	1.55	1.54	1.52	1.51	1.50	1.49	1.47	1.46	1.45
68.9	1.77	1.75	1.74	1.73	1.72	1.70	1.69	1.68	1.67	1.65	1.64	1.63	1.62	1.60	1.59	1.58	1.56	1.55	1.54	1.53	1.51	1.50	1.49	1.48	1.46
69.3	1.78	1.77	1.76	1.74	1.73	1.72	1.71	1.69	1.68	1.67	1.66	1.64	1.63	1.62	1.61	1.59	1.58	1.57	1.56	1.54	1.53	1.52	1.51	1.49	1.48
69.7	1.80	1.79	1.77	1.76	1.75	1.74	1.72	1.71	1.70	1.69	1.67	1.66	1.65	1.64	1.62	1.61	1.60	1.59	1.57	1.56	1.55	1.53	1.52	1.51	1.50
70.1	1.82	1.80	1.79	1.78	1.76	1.75	1.74	1.73	1.71	1.70	1.69	1.68	1.66	1.65	1.64	1.63	1.61	1.60	1.59	1.58	1.56	1.55	1.54	1.53	1.51
70.5	1.83	1.82	1.81	1.79	1.78	1.77	1.76	1.74	1.73	1.72	1.71	1.69	1.68	1.67	1.65	1.64	1.63	1.62	1.60	1.59	1.58	1.57	1.55	1.54	1.53
70.9	1.85	1.83	1.82	1.81	1.80	1.78	1.77	1.76	1.75	1.73	1.72	1.71	1.70	1.68	1.67	1.66	1.65	1.63	1.62	1.61	1.60	1.58	1.57	1.56	1.55
71.3	1.86	1.85	1.84	1.83	1.81	1.80	1.79	1.78	1.76	1.75	1.74	1.73	1.71	1.70	1.69	1.67	1.66	1.65	1.64	1.62	1.61	1.60	1.59	1.57	1.56
71.7	1.88	1.87	1.85	1.84	1.83	1.82	1.80	1.79	1.78	1.77	1.75	1.74	1.73	1.72	1.70	1.69	1.68	1.67	1.65	1.64	1.63	1.62	1.60	1.59	1.58
72.0	1.90	1.88	1.87	1.86	1.85	1.83	1.82	1.81	1.80	1.78	1.77	1.76	1.74	1.73	1.72	1.71	1.69	1.68	1.67	1.66	1.64	1.63	1.62	1.61	1.59
72.4	1.91	1.90	1.89	1.87	1.86	1.85	1.84	1.82	1.81	1.80	1.79	1.77	1.76	1.75	1.74	1.72	1.71	1.70	1.69	1.67	1.66	1.65	1.63	1.62	1.61
72.8	1.93	1.92	1.90	1.89	1.88	1.87	1.85	1.84	1.83	1.82	1.80	1.79	1.78	1.76	1.75	1.74	1.73	1.72	1.70	1.69	1.68	1.66	1.65	1.64	1.63
73.2	1.94	1.93	1.92	1.91	1.89	1.88	1.87	1.86	1.84	1.83	1.82	1.81	1.79	1.78	1.77	1.75	1.74	1.73	1.72	1.71	1.69	1.68	1.67	1.65	1.64
73.6	1.96	1.95	1.94	1.92	1.91	1.90	1.89	1.87	1.86	1.85	1.83	1.82	1.81	1.80	1.78	1.77	1.76	1.75	1.73	1.72	1.71	1.70	1.68	1.67	1.66
74.0	1.98	1.96	1.95	1.94	1.93	1.91	1.90	1.89	1.88	1.86	1.85	1.84	1.83	1.81	1.80	1.79	1.78	1.76	1.75	1.74	1.73	1.71	1.70	1.69	1.67
74.4	1.99	1.98	1.97	1.96	1.94	1.93	1.92	1.91	1.89	1.88	1.87	1.85	1.84	1.83	1.82	1.80	1.79	1.78	1.77	1.75	1.74	1.73	1.72	1.70	1.69
74.8	2.01	2.00	1.98	1.97	1.96	1.95	1.93	1.92	1.91	1.90	1.88	1.87	1.86	1.85	1.83	1.82	1.81	1.80	1.78	1.77	1.76	1.74	1.73	1.72	1.71

PREDICTION EQUATIONS FOR FVC — MALES — * 60% OF PREDICTED **

HEIGHT (IN)	AGE (YEARS) 22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46
59.1	2.22	2.27	2.32	2.14	2.12	2.10	2.09	2.07	2.05	2.04	2.02	2.00	1.98	1.97	1.95	1.93	1.91	1.90	1.88	1.86	1.84	1.83	1.81	1.79	1.77
59.4	2.25	2.30	2.35	2.18	2.16	2.14	2.13	2.11	2.09	2.07	2.06	2.04	2.02	2.00	1.99	1.97	1.95	1.93	1.92	1.90	1.88	1.87	1.85	1.83	1.81
59.8	2.28	2.33	2.38	2.22	2.20	2.18	2.17	2.15	2.13	2.11	2.10	2.08	2.06	2.04	2.03	2.01	1.99	1.97	1.96	1.94	1.92	1.90	1.89	1.87	1.85
60.2	2.31	2.36	2.41	2.26	2.24	2.22	2.20	2.19	2.17	2.15	2.13	2.12	2.10	2.08	2.07	2.05	2.03	2.01	2.00	1.98	1.96	1.94	1.93	1.91	1.89
60.6	2.34	2.39	2.44	2.30	2.28	2.26	2.24	2.23	2.21	2.19	2.17	2.16	2.14	2.12	2.10	2.09	2.07	2.05	2.03	2.02	2.00	1.98	1.96	1.95	1.93
61.0	2.37	2.42	2.47	2.33	2.32	2.30	2.28	2.26	2.25	2.23	2.21	2.20	2.18	2.16	2.14	2.13	2.11	2.09	2.07	2.06	2.04	2.02	2.00	1.99	1.97
61.4	2.40	2.45	2.50	2.37	2.36	2.34	2.32	2.30	2.29	2.27	2.25	2.23	2.22	2.20	2.18	2.16	2.15	2.13	2.11	2.10	2.08	2.06	2.04	2.03	2.01
61.8	2.43	2.48	2.53	2.41	2.40	2.38	2.36	2.34	2.33	2.31	2.29	2.27	2.26	2.24	2.22	2.20	2.19	2.17	2.15	2.13	2.12	2.10	2.08	2.06	2.05
62.2	2.46	2.51	2.56	2.45	2.43	2.42	2.40	2.38	2.36	2.35	2.33	2.31	2.29	2.28	2.26	2.24	2.23	2.21	2.19	2.17	2.16	2.14	2.12	2.10	2.09
62.6	2.49	2.54	2.59	2.49	2.47	2.46	2.44	2.42	2.40	2.39	2.37	2.35	2.33	2.32	2.30	2.28	2.26	2.25	2.23	2.21	2.19	2.18	2.16	2.14	2.13
63.0	2.52	2.57	2.62	2.53	2.51	2.49	2.48	2.46	2.44	2.43	2.41	2.39	2.37	2.36	2.34	2.32	2.30	2.29	2.27	2.25	2.23	2.22	2.20	2.18	2.16
63.4	2.55	2.60	2.65	2.57	2.55	2.53	2.52	2.50	2.48	2.46	2.45	2.43	2.41	2.39	2.38	2.36	2.34	2.32	2.31	2.29	2.27	2.26	2.24	2.22	2.20
63.8	2.58	2.63	2.68	2.61	2.59	2.57	2.56	2.54	2.52	2.50	2.49	2.47	2.45	2.43	2.42	2.40	2.38	2.36	2.35	2.33	2.31	2.29	2.28	2.26	2.24
64.2	2.61	2.66	2.71	2.65	2.63	2.61	2.59	2.58	2.56	2.54	2.52	2.51	2.49	2.47	2.46	2.44	2.42	2.40	2.39	2.37	2.35	2.33	2.32	2.30	2.28
64.6	2.64	2.69	2.74	2.69	2.67	2.65	2.63	2.62	2.60	2.58	2.56	2.55	2.53	2.51	2.49	2.48	2.46	2.44	2.42	2.41	2.39	2.37	2.35	2.34	2.32
65.0	2.67	2.72	2.77	2.72	2.71	2.69	2.67	2.65	2.64	2.62	2.60	2.59	2.57	2.55	2.53	2.52	2.50	2.48	2.46	2.45	2.43	2.41	2.39	2.38	2.36
65.4	2.70	2.75	2.80	2.76	2.75	2.73	2.71	2.69	2.68	2.66	2.64	2.62	2.61	2.59	2.57	2.55	2.54	2.52	2.50	2.49	2.47	2.45	2.43	2.42	2.40
65.7	2.73	2.78	2.83	2.80	2.79	2.77	2.75	2.73	2.72	2.70	2.68	2.66	2.65	2.63	2.61	2.59	2.58	2.56	2.54	2.52	2.51	2.49	2.47	2.45	2.44
66.1	2.76	2.81	2.86	2.84	2.82	2.81	2.79	2.77	2.75	2.74	2.72	2.70	2.68	2.67	2.65	2.63	2.62	2.60	2.58	2.56	2.55	2.53	2.51	2.49	2.48
66.5	2.79	2.84	2.89	2.88	2.86	2.85	2.83	2.81	2.79	2.78	2.76	2.74	2.72	2.71	2.69	2.67	2.65	2.64	2.62	2.60	2.58	2.57	2.55	2.53	2.52
66.9	2.82	2.87	2.92	2.92	2.90	2.88	2.87	2.85	2.83	2.82	2.80	2.78	2.76	2.75	2.73	2.71	2.69	2.68	2.66	2.64	2.62	2.61	2.59	2.57	2.55
67.3	2.85	2.90	2.95	2.96	2.94	2.92	2.91	2.89	2.87	2.85	2.84	2.82	2.80	2.78	2.77	2.75	2.73	2.71	2.70	2.68	2.66	2.65	2.63	2.61	2.59
67.7	2.88	2.93	2.98	3.00	2.98	2.96	2.95	2.93	2.91	2.89	2.88	2.86	2.84	2.82	2.81	2.79	2.77	2.75	2.74	2.72	2.70	2.68	2.67	2.65	2.63
68.1	2.91	2.96	3.01	3.04	3.02	3.00	2.98	2.97	2.95	2.93	2.91	2.90	2.88	2.86	2.85	2.83	2.81	2.79	2.78	2.76	2.74	2.72	2.71	2.69	2.67
68.5	2.94	2.99	3.04	3.08	3.06	3.04	3.02	3.01	2.99	2.97	2.95	2.94	2.92	2.90	2.88	2.87	2.85	2.83	2.81	2.80	2.78	2.76	2.74	2.73	2.71
68.9	2.97	3.02	3.07	3.11	3.10	3.08	3.06	3.04	3.03	3.01	2.99	2.98	2.96	2.94	2.92	2.91	2.89	2.87	2.85	2.84	2.82	2.80	2.78	2.77	2.75
69.3	3.00	3.05	3.10	3.15	3.14	3.12	3.10	3.08	3.07	3.05	3.03	3.01	3.00	2.98	2.96	2.94	2.93	2.91	2.89	2.88	2.86	2.84	2.82	2.81	2.79
69.7	3.03	3.08	3.13	3.19	3.18	3.16	3.14	3.12	3.11	3.09	3.07	3.05	3.04	3.02	3.00	2.98	2.97	2.95	2.93	2.91	2.90	2.88	2.86	2.84	2.83
70.1	3.06	3.11	3.16	3.23	3.21	3.20	3.18	3.16	3.14	3.13	3.11	3.09	3.07	3.06	3.04	3.02	3.01	2.99	2.97	2.95	2.94	2.92	2.90	2.88	2.87
70.5	3.09	3.14	3.19	3.27	3.25	3.24	3.22	3.20	3.18	3.17	3.15	3.13	3.11	3.10	3.08	3.06	3.04	3.03	3.01	2.99	2.97	2.96	2.94	2.92	2.91
70.9	3.12	3.17	3.22	3.31	3.29	3.27	3.26	3.24	3.22	3.21	3.19	3.17	3.15	3.14	3.12	3.10	3.08	3.07	3.05	3.03	3.01	3.00	2.98	2.96	2.94
71.3	3.15	3.20	3.25	3.35	3.33	3.31	3.30	3.28	3.26	3.24	3.23	3.21	3.19	3.17	3.16	3.14	3.12	3.10	3.09	3.07	3.05	3.04	3.02	3.00	2.98
71.7	3.18	3.23	3.28	3.39	3.37	3.35	3.34	3.32	3.30	3.28	3.27	3.25	3.23	3.21	3.20	3.18	3.16	3.14	3.13	3.11	3.09	3.07	3.06	3.04	3.02
72.0	3.21	3.26	3.31	3.43	3.41	3.39	3.37	3.36	3.34	3.32	3.30	3.29	3.27	3.25	3.24	3.22	3.20	3.18	3.17	3.15	3.13	3.11	3.10	3.08	3.06
72.4	3.24	3.29	3.34	3.47	3.45	3.43	3.41	3.40	3.38	3.36	3.34	3.33	3.31	3.29	3.27	3.26	3.24	3.22	3.20	3.19	3.17	3.15	3.13	3.12	3.10
72.8	3.27	3.32	3.37	3.50	3.49	3.47	3.45	3.43	3.42	3.40	3.38	3.37	3.35	3.33	3.31	3.30	3.28	3.26	3.24	3.23	3.21	3.19	3.17	3.16	3.14
73.2	3.30	3.35	3.40	3.54	3.53	3.51	3.49	3.47	3.46	3.44	3.42	3.40	3.39	3.37	3.35	3.33	3.32	3.30	3.28	3.27	3.25	3.23	3.21	3.20	3.18
73.6	3.33	3.38	3.43	3.58	3.57	3.55	3.53	3.51	3.50	3.48	3.46	3.44	3.43	3.41	3.39	3.37	3.36	3.34	3.32	3.30	3.29	3.27	3.25	3.23	3.22
74.0	3.36	3.41	3.46	3.62	3.60	3.59	3.57	3.55	3.53	3.52	3.50	3.48	3.46	3.45	3.43	3.41	3.40	3.38	3.36	3.34	3.33	3.31	3.29	3.27	3.26
74.4	3.39	3.44	3.49	3.66	3.64	3.63	3.61	3.59	3.57	3.56	3.54	3.52	3.50	3.49	3.47	3.45	3.43	3.42	3.40	3.38	3.36	3.35	3.33	3.31	3.30
74.8	3.42	3.47	3.52	3.70	3.68	3.66	3.65	3.63	3.61	3.60	3.58	3.56	3.54	3.53	3.51	3.49	3.47	3.46	3.44	3.42	3.40	3.39	3.37	3.35	3.33
75.2	3.45	3.50	3.55	3.74	3.72	3.70	3.69	3.67	3.65	3.63	3.62	3.60	3.58	3.56	3.55	3.53	3.51	3.49	3.48	3.46	3.44	3.43	3.41	3.39	3.37
75.6	3.48	3.53	3.58	3.78	3.76	3.74	3.73	3.71	3.69	3.67	3.66	3.64	3.62	3.60	3.59	3.57	3.55	3.53	3.52	3.50	3.48	3.46	3.45	3.43	3.41
76.0	3.51	3.56	3.61	3.82	3.80	3.78	3.76	3.75	3.73	3.71	3.69	3.68	3.66	3.64	3.63	3.61	3.59	3.57	3.56	3.54	3.52	3.50	3.49	3.47	3.45
76.4	3.54	3.59	3.64	3.86	3.84	3.82	3.80	3.79	3.77	3.75	3.73	3.72	3.70	3.68	3.66	3.65	3.63	3.61	3.59	3.58	3.56	3.54	3.52	3.51	3.49
76.8	3.57	3.62	3.67	3.89	3.88	3.86	3.84	3.82	3.81	3.79	3.77	3.76	3.74	3.72	3.70	3.69	3.67	3.65	3.63	3.62	3.60	3.58	3.56	3.55	3.53
77.2	3.60	3.65	3.70	3.93	3.92	3.90	3.88	3.86	3.85	3.83	3.81	3.79	3.78	3.76	3.74	3.72	3.71	3.69	3.67	3.66	3.64	3.62	3.60	3.59	3.57
77.6	3.63	3.68	3.73	3.97	3.96	3.94	3.92	3.90	3.89	3.87	3.85	3.83	3.82	3.80	3.78	3.76	3.75	3.73	3.71	3.69	3.68	3.66	3.64	3.62	3.61
78.0	3.66	3.71	3.76	4.01	3.99	3.98	3.96	3.94	3.92	3.91	3.89	3.87	3.85	3.84	3.82	3.80	3.79	3.77	3.75	3.73	3.72	3.70	3.68	3.66	3.65
78.3	3.69	3.74	3.79	4.05	4.03	4.02	4.00	3.98	3.96	3.95	3.93	3.91	3.89	3.88	3.86	3.84	3.82	3.81	3.79	3.77	3.75	3.74	3.72	3.70	3.69
78.7	3.72	3.77	3.82	4.09	4.07	4.05	4.04	4.02	4.00	3.99	3.97	3.95	3.93	3.92	3.90	3.88	3.86	3.85	3.83	3.81	3.79	3.78	3.76	3.74	3.72
79.1	3.75	3.80	3.85	4.13	4.11	4.09	4.08	4.06	4.04	4.02	4.01	3.99	3.97	3.95	3.94	3.92	3.90	3.88	3.87	3.85	3.83	3.82	3.80	3.78	3.76
79.5	3.78	3.83	3.88	4.17	4.15	4.13	4.12	4.10	4.08	4.06	4.05	4.03	4.01	3.99	3.98	3.96	3.94	3.92	3.91	3.89	3.87	3.85	3.84	3.82	3.80
79.9	3.81	3.86	3.91	4.21	4.19	4.17	4.15	4.14	4.12	4.10	4.08	4.07	4.05	4.03	4.02	4.00	3.98	3.96	3.95	3.93	3.91	3.89	3.88	3.86	3.84
80.3	3.84	3.89	3.94	4.25	4.23	4.21	4.19	4.18	4.16	4.14	4.12	4.11	4.09	4.07	4.05	4.04	4.02	4.00	3.98	3.97	3.95	3.93	3.91	3.90	3.88
80.7	3.87	3.92	3.97	4.28	4.27	4.25	4.23	4.21	4.20	4.18	4.16	4.15	4.13	4.11	4.09	4.08	4.06	4.04	4.02	4.01	3.99	3.97	3.95	3.94	3.92
81.1	3.90	3.95	4.00	4.32	4.31	4.29	4.27	4.25	4.24	4.22	4.20	4.18	4.17	4.15	4.13	4.11	4.10	4.08	4.06	4.05	4.03	4.01	3.99	3.98	3.96
81.5	3.93	3.98	4.03	4.36	4.35	4.33	4.31	4.29	4.28	4.26	4.24	4.22	4.21	4.19	4.17	4.15	4.14	4.12	4.10	4.08	4.07	4.05	4.03	4.01	4.00
81.9	3.96	4.01	4.06	4.40	4.38	4.37	4.35	4.33	4.31	4.30	4.28	4.26	4.24	4.23	4.21	4.19	4.18	4.16	4.14	4.12	4.11	4.09	4.07	4.05	4.04
82.3	3.99	4.04	4.09	4.44	4.42	4.41	4.39	4.37	4.35	4.34	4.32	4.30	4.28	4.27	4.25	4.23	4.21	4.20	4.18	4.16	4.14	4.13	4.11	4.09	4.08
82.7	4.02	4.07	4.12	4.48	4.46	4.44	4.43	4.41	4.39	4.38	4.36	4.34	4.32	4.31	4.29	4.27	4.25	4.24	4.22	4.20	4.18	4.17	4.15	4.13	4.11

PREDICTION EQUATIONS FOR FVC — MALES — * 80% OF PREDICTED **

AGE (YEARS)

HEIGHT (IN)	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71
59.1	1.76	1.74	1.72	1.70	1.69	1.67	1.65	1.63	1.62	1.60	1.58	1.57	1.55	1.53	1.51	1.50	1.48	1.46	1.44	1.43	1.41	1.39	1.37	1.36	1.34
59.4	1.80	1.78	1.76	1.74	1.73	1.71	1.69	1.67	1.66	1.64	1.62	1.60	1.59	1.57	1.55	1.53	1.52	1.50	1.48	1.47	1.45	1.43	1.41	1.40	1.38
59.8	1.83	1.82	1.80	1.78	1.77	1.75	1.73	1.71	1.70	1.68	1.66	1.64	1.63	1.61	1.59	1.57	1.56	1.54	1.52	1.50	1.49	1.47	1.45	1.43	1.42
60.2	1.87	1.86	1.84	1.82	1.80	1.79	1.77	1.75	1.73	1.72	1.70	1.68	1.66	1.65	1.63	1.61	1.59	1.58	1.56	1.54	1.53	1.51	1.49	1.47	1.46
60.6	1.91	1.90	1.88	1.86	1.84	1.83	1.81	1.79	1.77	1.76	1.74	1.72	1.70	1.69	1.67	1.65	1.63	1.62	1.60	1.58	1.56	1.55	1.53	1.51	1.50
61.0	1.95	1.93	1.92	1.90	1.88	1.86	1.85	1.83	1.81	1.79	1.78	1.76	1.74	1.73	1.71	1.69	1.67	1.66	1.64	1.62	1.60	1.59	1.57	1.55	1.53
61.4	1.99	1.97	1.96	1.94	1.92	1.90	1.89	1.87	1.85	1.83	1.82	1.80	1.78	1.76	1.75	1.73	1.71	1.69	1.68	1.66	1.64	1.62	1.61	1.59	1.57
61.8	2.03	2.01	2.00	1.98	1.96	1.94	1.93	1.91	1.89	1.87	1.86	1.84	1.82	1.80	1.79	1.77	1.75	1.73	1.72	1.70	1.68	1.66	1.65	1.63	1.61
62.2	2.07	2.05	2.03	2.02	2.00	1.98	1.96	1.95	1.93	1.91	1.89	1.88	1.86	1.84	1.82	1.81	1.79	1.77	1.76	1.74	1.72	1.70	1.68	1.67	1.65
62.6	2.11	2.09	2.07	2.06	2.04	2.02	2.00	1.99	1.97	1.95	1.93	1.92	1.90	1.88	1.86	1.85	1.83	1.81	1.79	1.78	1.76	1.74	1.72	1.71	1.69
63.0	2.15	2.13	2.11	2.09	2.08	2.06	2.04	2.02	2.01	1.99	1.97	1.96	1.94	1.92	1.90	1.89	1.87	1.85	1.83	1.82	1.80	1.78	1.76	1.75	1.73
63.4	2.19	2.17	2.15	2.13	2.12	2.10	2.08	2.06	2.05	2.03	2.01	1.99	1.98	1.96	1.94	1.92	1.91	1.89	1.87	1.85	1.84	1.82	1.80	1.78	1.77
63.8	2.22	2.21	2.19	2.17	2.16	2.14	2.12	2.10	2.09	2.07	2.05	2.03	2.02	2.00	1.98	1.96	1.95	1.93	1.91	1.89	1.88	1.86	1.84	1.82	1.81
64.2	2.26	2.25	2.23	2.21	2.19	2.18	2.16	2.14	2.12	2.11	2.09	2.07	2.05	2.04	2.02	2.00	1.98	1.97	1.95	1.93	1.91	1.90	1.88	1.86	1.85
64.6	2.30	2.29	2.27	2.25	2.23	2.22	2.20	2.18	2.16	2.15	2.13	2.11	2.09	2.08	2.06	2.04	2.02	2.01	1.99	1.97	1.95	1.94	1.92	1.90	1.88
65.0	2.34	2.32	2.31	2.29	2.27	2.25	2.24	2.22	2.20	2.18	2.17	2.15	2.13	2.12	2.10	2.08	2.06	2.05	2.03	2.01	1.99	1.98	1.96	1.94	1.92
65.4	2.38	2.36	2.35	2.33	2.31	2.29	2.28	2.26	2.24	2.22	2.21	2.19	2.17	2.15	2.14	2.12	2.10	2.08	2.07	2.05	2.03	2.01	2.00	1.98	1.96
65.7	2.42	2.40	2.39	2.37	2.35	2.33	2.32	2.30	2.28	2.26	2.25	2.23	2.21	2.19	2.18	2.16	2.14	2.12	2.11	2.09	2.07	2.05	2.04	2.02	2.00
66.1	2.46	2.44	2.42	2.41	2.39	2.37	2.35	2.34	2.32	2.30	2.28	2.27	2.25	2.23	2.21	2.20	2.18	2.16	2.14	2.13	2.11	2.09	2.08	2.06	2.04
66.5	2.50	2.48	2.46	2.45	2.43	2.41	2.39	2.38	2.36	2.34	2.32	2.31	2.29	2.27	2.25	2.24	2.22	2.20	2.18	2.17	2.15	2.13	2.11	2.10	2.08
66.9	2.54	2.52	2.50	2.48	2.47	2.45	2.43	2.41	2.40	2.38	2.36	2.35	2.33	2.31	2.29	2.28	2.26	2.24	2.22	2.21	2.19	2.17	2.15	2.14	2.12
67.3	2.58	2.56	2.54	2.52	2.51	2.49	2.47	2.45	2.44	2.42	2.40	2.38	2.37	2.35	2.33	2.31	2.30	2.28	2.26	2.24	2.23	2.21	2.19	2.17	2.16
67.7	2.61	2.60	2.58	2.56	2.55	2.53	2.51	2.49	2.48	2.46	2.44	2.42	2.41	2.39	2.37	2.35	2.34	2.32	2.30	2.28	2.27	2.25	2.23	2.21	2.20
68.1	2.65	2.64	2.62	2.60	2.58	2.57	2.55	2.53	2.51	2.50	2.48	2.46	2.44	2.43	2.41	2.39	2.37	2.36	2.34	2.32	2.30	2.29	2.27	2.25	2.24
68.5	2.69	2.68	2.66	2.64	2.62	2.61	2.59	2.57	2.55	2.54	2.52	2.50	2.48	2.47	2.45	2.43	2.41	2.40	2.38	2.36	2.34	2.33	2.31	2.29	2.27
68.9	2.73	2.71	2.70	2.68	2.66	2.64	2.63	2.61	2.59	2.57	2.56	2.54	2.52	2.51	2.49	2.47	2.45	2.44	2.42	2.40	2.38	2.37	2.35	2.33	2.31
69.3	2.77	2.75	2.74	2.72	2.70	2.68	2.67	2.65	2.63	2.61	2.60	2.58	2.56	2.54	2.53	2.51	2.49	2.47	2.46	2.44	2.42	2.40	2.39	2.37	2.35
69.7	2.81	2.79	2.78	2.76	2.74	2.72	2.71	2.69	2.67	2.65	2.64	2.62	2.60	2.58	2.57	2.55	2.53	2.51	2.50	2.48	2.46	2.44	2.43	2.41	2.39
70.1	2.85	2.83	2.81	2.80	2.78	2.76	2.74	2.73	2.71	2.69	2.67	2.66	2.64	2.62	2.60	2.59	2.57	2.55	2.53	2.52	2.50	2.48	2.47	2.45	2.43
70.5	2.89	2.87	2.85	2.84	2.82	2.80	2.78	2.77	2.75	2.73	2.71	2.70	2.68	2.66	2.64	2.63	2.61	2.59	2.57	2.56	2.54	2.52	2.50	2.49	2.47
70.9	2.93	2.91	2.89	2.87	2.86	2.84	2.82	2.80	2.79	2.77	2.75	2.74	2.72	2.70	2.68	2.67	2.65	2.63	2.61	2.60	2.58	2.56	2.54	2.53	2.51
71.3	2.97	2.95	2.93	2.91	2.90	2.88	2.86	2.84	2.83	2.81	2.79	2.77	2.76	2.74	2.72	2.70	2.69	2.67	2.65	2.63	2.62	2.60	2.58	2.56	2.55
71.7	3.00	2.99	2.97	2.95	2.94	2.92	2.90	2.88	2.87	2.85	2.83	2.81	2.80	2.78	2.76	2.74	2.73	2.71	2.69	2.67	2.66	2.64	2.62	2.60	2.59
72.0	3.04	3.03	3.01	2.99	2.97	2.96	2.94	2.92	2.90	2.89	2.87	2.85	2.83	2.82	2.80	2.78	2.76	2.75	2.73	2.71	2.69	2.68	2.66	2.64	2.63
72.4	3.08	3.07	3.05	3.03	3.01	3.00	2.98	2.96	2.94	2.93	2.91	2.89	2.87	2.86	2.84	2.82	2.80	2.79	2.77	2.75	2.73	2.72	2.70	2.68	2.66
72.8	3.12	3.10	3.09	3.07	3.05	3.03	3.02	3.00	2.98	2.96	2.95	2.93	2.91	2.90	2.88	2.86	2.84	2.83	2.81	2.79	2.77	2.76	2.74	2.72	2.70
73.2	3.16	3.14	3.13	3.11	3.09	3.07	3.06	3.04	3.02	3.00	2.99	2.97	2.95	2.93	2.92	2.90	2.88	2.86	2.85	2.83	2.81	2.79	2.78	2.76	2.74
73.6	3.20	3.18	3.17	3.15	3.13	3.11	3.10	3.08	3.06	3.04	3.03	3.01	2.99	2.97	2.96	2.94	2.92	2.90	2.89	2.87	2.85	2.83	2.82	2.80	2.78
74.0	3.24	3.22	3.20	3.19	3.17	3.15	3.13	3.12	3.10	3.08	3.06	3.05	3.03	3.01	2.99	2.98	2.96	2.94	2.92	2.91	2.89	2.87	2.86	2.84	2.82
74.4	3.28	3.26	3.24	3.23	3.21	3.19	3.17	3.16	3.14	3.12	3.10	3.09	3.07	3.05	3.03	3.02	3.00	2.98	2.96	2.95	2.93	2.91	2.89	2.88	2.86
74.8	3.32	3.30	3.28	3.26	3.25	3.23	3.21	3.19	3.18	3.16	3.14	3.13	3.11	3.09	3.07	3.06	3.04	3.02	3.00	2.99	2.97	2.95	2.93	2.92	2.90
75.2	3.36	3.34	3.32	3.30	3.29	3.27	3.25	3.23	3.22	3.20	3.18	3.16	3.15	3.13	3.11	3.09	3.08	3.06	3.04	3.02	3.01	2.99	2.97	2.95	2.94
75.6	3.39	3.38	3.36	3.34	3.33	3.31	3.29	3.27	3.26	3.24	3.22	3.20	3.19	3.17	3.15	3.13	3.12	3.10	3.08	3.06	3.05	3.03	3.01	2.99	2.98
76.0	3.43	3.42	3.40	3.38	3.36	3.35	3.33	3.31	3.29	3.28	3.26	3.24	3.22	3.21	3.19	3.17	3.15	3.14	3.12	3.10	3.08	3.07	3.05	3.03	3.02
76.4	3.47	3.46	3.44	3.42	3.40	3.39	3.37	3.35	3.33	3.32	3.30	3.28	3.26	3.25	3.23	3.21	3.19	3.18	3.16	3.14	3.12	3.11	3.09	3.07	3.05
76.8	3.51	3.49	3.48	3.46	3.44	3.42	3.41	3.39	3.37	3.35	3.34	3.32	3.30	3.29	3.27	3.25	3.23	3.22	3.20	3.18	3.16	3.15	3.13	3.11	3.09
77.2	3.55	3.53	3.52	3.50	3.48	3.46	3.45	3.43	3.41	3.39	3.38	3.36	3.34	3.32	3.31	3.29	3.27	3.25	3.24	3.22	3.20	3.18	3.17	3.15	3.13
77.6	3.59	3.57	3.56	3.54	3.52	3.50	3.49	3.47	3.45	3.43	3.42	3.40	3.38	3.36	3.35	3.33	3.31	3.29	3.28	3.26	3.24	3.22	3.21	3.19	3.17
78.0	3.63	3.61	3.59	3.58	3.56	3.54	3.52	3.51	3.49	3.47	3.45	3.44	3.42	3.40	3.38	3.37	3.35	3.33	3.31	3.30	3.28	3.26	3.25	3.23	3.21
78.3	3.67	3.65	3.63	3.62	3.60	3.58	3.56	3.55	3.53	3.51	3.49	3.48	3.46	3.44	3.42	3.41	3.39	3.37	3.35	3.34	3.32	3.30	3.28	3.27	3.25
78.7	3.71	3.69	3.67	3.65	3.64	3.62	3.60	3.58	3.57	3.55	3.53	3.52	3.50	3.48	3.46	3.45	3.43	3.41	3.39	3.38	3.36	3.34	3.32	3.31	3.29
79.1	3.75	3.73	3.71	3.69	3.68	3.66	3.64	3.62	3.61	3.59	3.57	3.55	3.54	3.52	3.50	3.48	3.47	3.45	3.43	3.41	3.40	3.38	3.36	3.34	3.33
79.5	3.78	3.77	3.75	3.73	3.72	3.70	3.68	3.66	3.65	3.63	3.61	3.59	3.58	3.56	3.54	3.52	3.51	3.49	3.47	3.45	3.44	3.42	3.40	3.38	3.37
79.9	3.82	3.81	3.79	3.77	3.75	3.74	3.72	3.70	3.68	3.67	3.65	3.63	3.61	3.60	3.58	3.56	3.54	3.53	3.51	3.49	3.47	3.46	3.44	3.42	3.41
80.3	3.86	3.85	3.83	3.81	3.79	3.78	3.76	3.74	3.72	3.71	3.69	3.67	3.65	3.64	3.62	3.60	3.58	3.57	3.55	3.53	3.51	3.50	3.48	3.46	3.44
80.7	3.90	3.88	3.87	3.85	3.83	3.81	3.80	3.78	3.76	3.74	3.73	3.71	3.69	3.68	3.66	3.64	3.62	3.61	3.59	3.57	3.55	3.54	3.52	3.50	3.48
81.1	3.94	3.92	3.91	3.89	3.87	3.85	3.84	3.82	3.80	3.78	3.77	3.75	3.73	3.71	3.70	3.68	3.66	3.64	3.63	3.61	3.59	3.57	3.56	3.54	3.52
81.5	3.98	3.96	3.95	3.93	3.91	3.89	3.88	3.86	3.84	3.82	3.81	3.79	3.77	3.75	3.74	3.72	3.70	3.68	3.67	3.65	3.63	3.61	3.60	3.58	3.56
81.9	4.02	4.00	3.98	3.97	3.95	3.93	3.91	3.90	3.88	3.86	3.84	3.83	3.81	3.79	3.77	3.76	3.74	3.72	3.70	3.69	3.67	3.65	3.64	3.62	3.60
82.3	4.06	4.04	4.02	4.01	3.99	3.97	3.95	3.94	3.92	3.90	3.88	3.87	3.85	3.83	3.81	3.80	3.78	3.76	3.74	3.73	3.71	3.69	3.67	3.66	3.64
82.7	4.10	4.08	4.06	4.04	4.03	4.01	3.99	3.97	3.96	3.94	3.92	3.91	3.89	3.87	3.85	3.84	3.82	3.80	3.78	3.77	3.75	3.73	3.71	3.70	3.68

157-066 O—95——25

PREDICTION EQUATIONS FOR FVC FEMALES * 80% OF PREDICTED **

HEIGHT (IN)	AGE (YEARS) 22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46
51.2	1.53	1.52	1.50	1.49	1.48	1.47	1.45	1.44	1.43	1.41	1.40	1.39	1.37	1.36	1.35	1.33	1.32	1.31	1.29	1.28	1.27	1.25	1.24	1.23	1.21
51.6	1.55	1.54	1.53	1.51	1.50	1.49	1.47	1.46	1.45	1.43	1.42	1.41	1.40	1.38	1.37	1.36	1.34	1.33	1.32	1.30	1.29	1.28	1.26	1.25	1.24
52.0	1.58	1.56	1.55	1.54	1.52	1.51	1.50	1.48	1.47	1.46	1.44	1.43	1.42	1.40	1.39	1.38	1.36	1.35	1.34	1.32	1.31	1.30	1.29	1.27	1.26
52.4	1.60	1.58	1.57	1.56	1.54	1.53	1.52	1.51	1.49	1.48	1.47	1.45	1.44	1.43	1.41	1.40	1.39	1.37	1.36	1.35	1.33	1.32	1.31	1.29	1.28
52.8	1.62	1.61	1.59	1.58	1.57	1.55	1.54	1.53	1.51	1.50	1.49	1.47	1.46	1.45	1.44	1.42	1.41	1.40	1.38	1.37	1.36	1.34	1.33	1.32	1.30
53.1	1.64	1.63	1.62	1.60	1.59	1.58	1.56	1.55	1.54	1.52	1.51	1.50	1.48	1.47	1.46	1.44	1.43	1.42	1.40	1.39	1.38	1.37	1.35	1.34	1.33
53.5	1.66	1.65	1.64	1.62	1.61	1.60	1.59	1.57	1.56	1.55	1.53	1.52	1.51	1.49	1.48	1.47	1.45	1.44	1.43	1.41	1.40	1.39	1.37	1.36	1.35
53.9	1.69	1.67	1.66	1.65	1.63	1.62	1.61	1.59	1.58	1.57	1.55	1.54	1.53	1.52	1.50	1.49	1.48	1.46	1.45	1.44	1.42	1.41	1.40	1.38	1.37
54.3	1.71	1.70	1.68	1.67	1.66	1.64	1.63	1.62	1.60	1.59	1.58	1.56	1.55	1.54	1.52	1.51	1.50	1.49	1.47	1.46	1.44	1.43	1.42	1.41	1.39
54.7	1.73	1.72	1.70	1.69	1.68	1.67	1.65	1.64	1.63	1.61	1.60	1.59	1.57	1.56	1.55	1.53	1.52	1.51	1.49	1.48	1.47	1.45	1.44	1.43	1.41
55.1	1.75	1.74	1.73	1.71	1.70	1.69	1.67	1.66	1.65	1.63	1.62	1.61	1.59	1.58	1.57	1.56	1.54	1.53	1.52	1.50	1.49	1.48	1.46	1.45	1.44
55.5	1.78	1.76	1.75	1.74	1.72	1.71	1.70	1.68	1.67	1.66	1.64	1.63	1.62	1.60	1.59	1.58	1.56	1.55	1.54	1.52	1.51	1.50	1.49	1.47	1.46
55.9	1.80	1.78	1.77	1.76	1.74	1.73	1.72	1.71	1.69	1.68	1.67	1.65	1.64	1.63	1.61	1.60	1.59	1.57	1.56	1.55	1.53	1.52	1.51	1.49	1.48
56.3	1.82	1.81	1.79	1.78	1.77	1.75	1.74	1.73	1.71	1.70	1.69	1.67	1.66	1.65	1.63	1.62	1.61	1.60	1.58	1.57	1.56	1.54	1.53	1.52	1.50
56.7	1.84	1.83	1.82	1.80	1.79	1.78	1.76	1.75	1.74	1.72	1.71	1.70	1.68	1.67	1.66	1.64	1.63	1.62	1.60	1.59	1.58	1.56	1.55	1.54	1.53
57.1	1.86	1.85	1.84	1.82	1.81	1.80	1.79	1.77	1.76	1.75	1.73	1.72	1.71	1.69	1.68	1.67	1.65	1.64	1.63	1.61	1.60	1.59	1.57	1.56	1.55
57.5	1.89	1.87	1.86	1.85	1.83	1.82	1.81	1.79	1.78	1.77	1.75	1.74	1.73	1.71	1.70	1.69	1.68	1.66	1.65	1.64	1.62	1.61	1.60	1.58	1.57
57.9	1.91	1.90	1.88	1.87	1.86	1.84	1.83	1.82	1.80	1.79	1.78	1.76	1.75	1.74	1.72	1.71	1.70	1.68	1.67	1.66	1.64	1.63	1.62	1.61	1.59
58.3	1.93	1.92	1.90	1.89	1.88	1.86	1.85	1.84	1.83	1.81	1.80	1.79	1.77	1.76	1.75	1.73	1.72	1.71	1.69	1.68	1.67	1.65	1.64	1.63	1.61
58.7	1.95	1.94	1.93	1.91	1.90	1.89	1.87	1.86	1.85	1.83	1.82	1.81	1.79	1.78	1.77	1.75	1.74	1.73	1.72	1.70	1.69	1.68	1.66	1.65	1.64
59.1	1.98	1.96	1.95	1.94	1.92	1.91	1.90	1.88	1.87	1.86	1.84	1.83	1.82	1.80	1.79	1.78	1.76	1.75	1.74	1.72	1.71	1.70	1.68	1.67	1.66
59.4	2.00	1.98	1.97	1.96	1.94	1.93	1.92	1.90	1.89	1.88	1.86	1.85	1.84	1.82	1.81	1.80	1.79	1.77	1.76	1.75	1.73	1.72	1.71	1.69	1.68
59.8	2.02	2.01	1.99	1.98	1.97	1.95	1.94	1.93	1.91	1.90	1.89	1.87	1.86	1.85	1.83	1.82	1.81	1.79	1.78	1.77	1.75	1.74	1.73	1.71	1.70
60.2	2.04	2.03	2.02	2.00	1.99	1.98	1.96	1.95	1.94	1.92	1.91	1.90	1.88	1.87	1.86	1.84	1.83	1.82	1.80	1.79	1.78	1.76	1.75	1.74	1.73
60.6	2.06	2.05	2.04	2.02	2.01	2.00	1.98	1.97	1.96	1.95	1.93	1.92	1.91	1.89	1.88	1.87	1.85	1.84	1.83	1.81	1.80	1.79	1.78	1.76	1.75
61.0	2.09	2.07	2.06	2.05	2.03	2.02	2.01	1.99	1.98	1.97	1.95	1.94	1.93	1.91	1.90	1.89	1.88	1.86	1.85	1.84	1.82	1.81	1.80	1.78	1.77
61.4	2.11	2.10	2.08	2.07	2.06	2.04	2.03	2.02	2.00	1.99	1.98	1.96	1.95	1.94	1.92	1.91	1.90	1.88	1.87	1.86	1.84	1.83	1.82	1.81	1.79
61.8	2.13	2.12	2.10	2.09	2.08	2.06	2.05	2.04	2.03	2.01	2.00	1.99	1.97	1.96	1.95	1.93	1.92	1.91	1.89	1.88	1.87	1.85	1.84	1.83	1.81
62.2	2.15	2.14	2.13	2.11	2.10	2.09	2.07	2.06	2.05	2.03	2.02	2.01	1.99	1.98	1.97	1.95	1.94	1.93	1.92	1.90	1.89	1.88	1.86	1.85	1.84
62.6	2.17	2.16	2.15	2.13	2.12	2.11	2.10	2.08	2.07	2.06	2.04	2.03	2.02	2.00	1.99	1.98	1.96	1.95	1.94	1.92	1.91	1.90	1.88	1.87	1.86
63.0	2.20	2.18	2.17	2.16	2.14	2.13	2.12	2.10	2.09	2.08	2.07	2.05	2.04	2.03	2.01	2.00	1.99	1.97	1.96	1.95	1.93	1.92	1.91	1.89	1.88
63.4	2.22	2.21	2.19	2.18	2.17	2.15	2.14	2.13	2.11	2.10	2.09	2.07	2.06	2.05	2.03	2.02	2.01	2.00	1.98	1.97	1.96	1.94	1.93	1.92	1.90
63.8	2.24	2.23	2.21	2.20	2.19	2.18	2.16	2.15	2.14	2.12	2.11	2.10	2.08	2.07	2.06	2.04	2.03	2.02	2.00	1.99	1.98	1.96	1.95	1.94	1.93
64.2	2.26	2.25	2.24	2.22	2.21	2.20	2.18	2.17	2.16	2.15	2.13	2.12	2.11	2.09	2.08	2.07	2.05	2.04	2.03	2.01	2.00	1.99	1.97	1.96	1.95
64.6	2.29	2.27	2.26	2.25	2.23	2.22	2.21	2.19	2.18	2.17	2.15	2.14	2.13	2.11	2.10	2.09	2.07	2.06	2.05	2.04	2.02	2.01	2.00	1.98	1.97
65.0	2.31	2.30	2.28	2.27	2.26	2.24	2.23	2.22	2.20	2.19	2.18	2.16	2.15	2.14	2.12	2.11	2.10	2.08	2.07	2.06	2.04	2.03	2.02	2.00	1.99
65.4	2.33	2.32	2.30	2.29	2.28	2.26	2.25	2.24	2.23	2.21	2.20	2.19	2.17	2.16	2.15	2.13	2.12	2.11	2.09	2.08	2.07	2.05	2.04	2.03	2.01
65.7	2.35	2.34	2.33	2.31	2.30	2.29	2.27	2.26	2.25	2.23	2.22	2.21	2.19	2.18	2.17	2.15	2.14	2.13	2.12	2.10	2.09	2.08	2.06	2.05	2.04
66.1	2.37	2.36	2.35	2.34	2.32	2.31	2.30	2.28	2.27	2.26	2.24	2.23	2.22	2.20	2.19	2.18	2.16	2.15	2.14	2.12	2.11	2.10	2.08	2.07	2.06
66.5	2.40	2.38	2.37	2.36	2.34	2.33	2.32	2.30	2.29	2.28	2.27	2.25	2.24	2.23	2.21	2.20	2.19	2.17	2.16	2.15	2.13	2.12	2.11	2.09	2.08
66.9	2.42	2.41	2.39	2.38	2.37	2.35	2.34	2.33	2.31	2.30	2.29	2.27	2.26	2.25	2.23	2.22	2.21	2.20	2.18	2.17	2.16	2.14	2.13	2.12	2.10
67.3	2.44	2.43	2.42	2.40	2.39	2.38	2.36	2.35	2.34	2.32	2.31	2.30	2.28	2.27	2.26	2.24	2.23	2.22	2.20	2.19	2.18	2.16	2.15	2.14	2.12
67.7	2.46	2.45	2.44	2.42	2.41	2.40	2.38	2.37	2.36	2.35	2.33	2.32	2.31	2.29	2.28	2.27	2.25	2.24	2.23	2.21	2.20	2.19	2.17	2.16	2.15
68.1	2.49	2.47	2.46	2.45	2.43	2.42	2.41	2.39	2.38	2.37	2.35	2.34	2.33	2.31	2.30	2.29	2.27	2.26	2.25	2.24	2.22	2.21	2.20	2.18	2.17
68.5	2.51	2.49	2.48	2.47	2.46	2.44	2.43	2.42	2.40	2.39	2.38	2.36	2.35	2.34	2.32	2.31	2.30	2.28	2.27	2.26	2.24	2.23	2.22	2.20	2.19
68.9	2.53	2.52	2.50	2.49	2.48	2.46	2.45	2.44	2.43	2.41	2.40	2.39	2.37	2.36	2.35	2.33	2.32	2.31	2.29	2.28	2.27	2.25	2.24	2.23	2.21
69.3	2.55	2.54	2.53	2.51	2.50	2.49	2.47	2.46	2.45	2.43	2.42	2.41	2.39	2.38	2.37	2.35	2.34	2.33	2.32	2.30	2.29	2.28	2.26	2.25	2.24
69.7	2.57	2.56	2.55	2.54	2.52	2.51	2.50	2.48	2.47	2.46	2.44	2.43	2.42	2.40	2.39	2.38	2.36	2.35	2.34	2.32	2.31	2.30	2.28	2.27	2.26
70.1	2.60	2.58	2.57	2.56	2.54	2.53	2.52	2.50	2.49	2.48	2.47	2.45	2.44	2.43	2.41	2.40	2.39	2.37	2.36	2.35	2.33	2.32	2.31	2.29	2.28
70.5	2.62	2.61	2.59	2.58	2.57	2.55	2.54	2.53	2.51	2.50	2.49	2.47	2.46	2.45	2.43	2.42	2.41	2.40	2.38	2.37	2.36	2.34	2.33	2.32	2.30
70.9	2.64	2.63	2.61	2.60	2.59	2.58	2.56	2.55	2.54	2.52	2.51	2.50	2.48	2.47	2.46	2.44	2.43	2.42	2.40	2.39	2.38	2.36	2.35	2.34	2.33
71.3	2.66	2.65	2.64	2.62	2.61	2.60	2.58	2.57	2.56	2.55	2.53	2.52	2.51	2.49	2.48	2.47	2.45	2.44	2.43	2.41	2.40	2.39	2.37	2.36	2.35
71.7	2.69	2.67	2.66	2.65	2.63	2.62	2.61	2.59	2.58	2.57	2.55	2.54	2.53	2.51	2.50	2.49	2.47	2.46	2.45	2.44	2.42	2.41	2.40	2.38	2.37
72.0	2.71	2.69	2.68	2.67	2.65	2.64	2.63	2.62	2.60	2.59	2.58	2.56	2.55	2.54	2.52	2.51	2.50	2.48	2.47	2.46	2.44	2.43	2.42	2.40	2.39
72.4	2.73	2.72	2.70	2.69	2.68	2.66	2.65	2.64	2.62	2.61	2.60	2.58	2.57	2.56	2.55	2.53	2.52	2.51	2.49	2.48	2.47	2.45	2.44	2.43	2.41
72.8	2.75	2.74	2.73	2.71	2.70	2.69	2.67	2.66	2.65	2.63	2.62	2.61	2.59	2.58	2.57	2.55	2.54	2.53	2.51	2.50	2.49	2.48	2.46	2.45	2.44
73.2	2.77	2.76	2.75	2.74	2.72	2.71	2.70	2.68	2.67	2.66	2.64	2.63	2.62	2.60	2.59	2.58	2.56	2.55	2.54	2.52	2.51	2.50	2.48	2.47	2.46
73.6	2.80	2.78	2.77	2.76	2.74	2.73	2.72	2.70	2.69	2.68	2.66	2.65	2.64	2.63	2.61	2.60	2.59	2.57	2.56	2.55	2.53	2.52	2.51	2.49	2.48
74.0	2.82	2.81	2.79	2.78	2.77	2.75	2.74	2.73	2.71	2.70	2.69	2.67	2.66	2.65	2.63	2.62	2.61	2.59	2.58	2.57	2.55	2.54	2.53	2.52	2.50
74.4	2.84	2.83	2.81	2.80	2.79	2.78	2.76	2.75	2.74	2.72	2.71	2.70	2.68	2.67	2.66	2.64	2.63	2.62	2.60	2.59	2.58	2.56	2.55	2.54	2.52
74.8	2.86	2.85	2.84	2.83	2.81	2.80	2.78	2.77	2.76	2.74	2.73	2.72	2.70	2.69	2.68	2.67	2.65	2.64	2.63	2.61	2.60	2.59	2.57	2.56	2.55

PREDICTION EQUATIONS FOR FVC FEMALES * BUS OF PREDICTED **

HEIGHT (IN)	AGE (YEARS) 47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71
51.2	1.20	1.19	1.17	1.16	1.15	1.14	1.12	1.11	1.10	1.08	1.07	1.06	1.04	1.03	1.02	1.00	0.99	0.98	0.96	0.95	0.94	0.92	0.91	0.90	0.88
51.6	1.22	1.21	1.20	1.18	1.17	1.16	1.14	1.13	1.12	1.10	1.09	1.08	1.07	1.05	1.04	1.03	1.01	1.00	0.99	0.97	0.96	0.95	0.93	0.92	0.91
52.0	1.25	1.23	1.22	1.21	1.19	1.18	1.17	1.15	1.14	1.13	1.11	1.10	1.09	1.07	1.06	1.05	1.03	1.02	1.01	0.99	0.98	0.97	0.95	0.94	0.93
52.4	1.27	1.25	1.24	1.23	1.21	1.20	1.19	1.18	1.16	1.15	1.14	1.12	1.11	1.10	1.08	1.07	1.06	1.04	1.03	1.02	1.00	0.99	0.98	0.96	0.95
52.8	1.29	1.28	1.26	1.25	1.24	1.22	1.21	1.20	1.18	1.17	1.16	1.14	1.13	1.12	1.11	1.09	1.08	1.07	1.05	1.04	1.03	1.01	1.00	0.99	0.97
53.1	1.31	1.30	1.29	1.27	1.26	1.25	1.23	1.22	1.21	1.19	1.18	1.17	1.15	1.14	1.13	1.11	1.10	1.09	1.07	1.06	1.05	1.03	1.02	1.01	1.00
53.5	1.33	1.32	1.31	1.29	1.28	1.27	1.26	1.24	1.23	1.22	1.20	1.19	1.18	1.16	1.15	1.14	1.12	1.11	1.10	1.08	1.07	1.06	1.04	1.03	1.02
53.9	1.36	1.34	1.33	1.32	1.30	1.29	1.28	1.26	1.25	1.24	1.22	1.21	1.20	1.19	1.17	1.16	1.15	1.13	1.12	1.11	1.09	1.08	1.07	1.05	1.04
54.3	1.38	1.37	1.35	1.34	1.33	1.31	1.30	1.29	1.27	1.26	1.25	1.23	1.22	1.21	1.19	1.18	1.17	1.15	1.14	1.13	1.11	1.10	1.09	1.08	1.06
54.7	1.40	1.39	1.37	1.36	1.35	1.34	1.32	1.31	1.30	1.28	1.27	1.26	1.24	1.23	1.22	1.20	1.19	1.18	1.16	1.15	1.14	1.12	1.11	1.10	1.08
55.1	1.42	1.41	1.40	1.38	1.37	1.36	1.34	1.33	1.32	1.30	1.29	1.28	1.26	1.25	1.24	1.22	1.21	1.20	1.19	1.17	1.16	1.15	1.13	1.12	1.11
55.5	1.45	1.43	1.42	1.41	1.39	1.38	1.37	1.35	1.34	1.33	1.31	1.30	1.29	1.27	1.26	1.25	1.23	1.22	1.21	1.19	1.18	1.17	1.15	1.14	1.13
55.9	1.47	1.45	1.44	1.43	1.41	1.40	1.39	1.38	1.36	1.35	1.34	1.32	1.31	1.30	1.28	1.27	1.26	1.24	1.23	1.22	1.20	1.19	1.18	1.16	1.15
56.3	1.49	1.48	1.46	1.45	1.44	1.42	1.41	1.40	1.38	1.37	1.36	1.34	1.33	1.32	1.30	1.29	1.28	1.26	1.25	1.24	1.22	1.21	1.20	1.18	1.17
56.7	1.51	1.50	1.49	1.47	1.46	1.45	1.43	1.42	1.41	1.39	1.38	1.37	1.35	1.34	1.33	1.31	1.30	1.29	1.27	1.26	1.25	1.23	1.22	1.21	1.19
57.1	1.53	1.52	1.51	1.49	1.48	1.47	1.46	1.44	1.43	1.42	1.40	1.39	1.38	1.36	1.35	1.34	1.32	1.31	1.30	1.28	1.27	1.26	1.24	1.23	1.22
57.5	1.56	1.54	1.53	1.52	1.50	1.49	1.48	1.46	1.45	1.44	1.42	1.41	1.40	1.38	1.37	1.36	1.35	1.33	1.32	1.31	1.29	1.28	1.27	1.25	1.24
57.9	1.58	1.57	1.55	1.54	1.53	1.51	1.50	1.49	1.47	1.46	1.45	1.43	1.42	1.41	1.39	1.38	1.37	1.35	1.34	1.33	1.31	1.30	1.29	1.27	1.26
58.3	1.60	1.59	1.57	1.56	1.55	1.53	1.52	1.51	1.50	1.48	1.47	1.46	1.44	1.43	1.42	1.40	1.39	1.38	1.36	1.35	1.34	1.32	1.31	1.30	1.28
58.7	1.62	1.61	1.60	1.58	1.57	1.56	1.54	1.53	1.52	1.50	1.49	1.48	1.46	1.45	1.44	1.42	1.41	1.40	1.38	1.37	1.36	1.35	1.33	1.32	1.31
59.1	1.65	1.63	1.62	1.61	1.59	1.58	1.57	1.55	1.54	1.53	1.51	1.50	1.49	1.47	1.46	1.45	1.43	1.42	1.41	1.39	1.38	1.37	1.35	1.34	1.33
59.4	1.67	1.65	1.64	1.63	1.61	1.60	1.59	1.57	1.56	1.55	1.54	1.52	1.51	1.50	1.48	1.47	1.46	1.44	1.43	1.42	1.40	1.39	1.38	1.36	1.35
59.8	1.69	1.68	1.66	1.65	1.64	1.62	1.61	1.60	1.58	1.57	1.56	1.54	1.53	1.52	1.50	1.49	1.48	1.46	1.45	1.44	1.42	1.41	1.40	1.39	1.37
60.2	1.71	1.70	1.69	1.67	1.66	1.65	1.63	1.62	1.61	1.59	1.58	1.57	1.55	1.54	1.53	1.51	1.50	1.49	1.47	1.46	1.45	1.43	1.42	1.41	1.39
60.6	1.73	1.72	1.71	1.69	1.68	1.67	1.65	1.64	1.63	1.62	1.60	1.59	1.58	1.56	1.55	1.54	1.52	1.51	1.50	1.48	1.47	1.46	1.44	1.43	1.42
61.0	1.76	1.74	1.73	1.72	1.70	1.69	1.68	1.66	1.65	1.64	1.62	1.61	1.60	1.58	1.57	1.56	1.55	1.53	1.52	1.51	1.49	1.48	1.47	1.45	1.44
61.4	1.78	1.77	1.75	1.74	1.73	1.71	1.70	1.69	1.67	1.66	1.65	1.63	1.62	1.61	1.59	1.58	1.57	1.55	1.54	1.53	1.51	1.50	1.49	1.47	1.46
61.8	1.80	1.79	1.77	1.76	1.75	1.73	1.72	1.71	1.70	1.68	1.67	1.66	1.64	1.63	1.62	1.60	1.59	1.58	1.56	1.55	1.54	1.52	1.51	1.50	1.48
62.2	1.82	1.81	1.80	1.78	1.77	1.76	1.74	1.73	1.72	1.70	1.69	1.68	1.66	1.65	1.64	1.62	1.61	1.60	1.58	1.57	1.56	1.55	1.53	1.52	1.51
62.6	1.84	1.83	1.82	1.81	1.79	1.78	1.77	1.75	1.74	1.73	1.71	1.70	1.69	1.67	1.66	1.65	1.63	1.62	1.61	1.59	1.58	1.57	1.55	1.54	1.53
63.0	1.87	1.85	1.84	1.83	1.81	1.80	1.79	1.77	1.76	1.75	1.74	1.72	1.71	1.70	1.68	1.67	1.66	1.64	1.63	1.62	1.60	1.59	1.58	1.56	1.55
63.4	1.89	1.88	1.86	1.85	1.84	1.82	1.81	1.80	1.78	1.77	1.76	1.74	1.73	1.72	1.70	1.69	1.68	1.66	1.65	1.64	1.62	1.61	1.60	1.58	1.57
63.8	1.91	1.90	1.89	1.87	1.86	1.85	1.83	1.82	1.81	1.79	1.78	1.77	1.75	1.74	1.73	1.71	1.70	1.69	1.67	1.66	1.65	1.63	1.62	1.61	1.59
64.2	1.93	1.92	1.91	1.89	1.88	1.87	1.85	1.84	1.83	1.82	1.80	1.79	1.78	1.76	1.75	1.74	1.72	1.71	1.70	1.68	1.67	1.66	1.64	1.63	1.62
64.6	1.96	1.94	1.93	1.92	1.90	1.89	1.88	1.86	1.85	1.84	1.82	1.81	1.80	1.78	1.77	1.76	1.75	1.73	1.72	1.71	1.69	1.68	1.67	1.65	1.64
65.0	1.98	1.97	1.95	1.94	1.93	1.91	1.90	1.89	1.87	1.86	1.85	1.83	1.82	1.81	1.79	1.78	1.77	1.75	1.74	1.73	1.71	1.70	1.69	1.67	1.66
65.4	2.00	1.99	1.97	1.96	1.95	1.94	1.92	1.91	1.90	1.88	1.87	1.86	1.84	1.83	1.82	1.80	1.79	1.78	1.76	1.75	1.74	1.72	1.71	1.70	1.68
65.7	2.02	2.01	2.00	1.98	1.97	1.96	1.94	1.93	1.92	1.90	1.89	1.88	1.86	1.85	1.84	1.82	1.81	1.80	1.78	1.77	1.76	1.75	1.73	1.72	1.71
66.1	2.04	2.03	2.02	2.01	1.99	1.98	1.97	1.95	1.94	1.93	1.91	1.90	1.89	1.87	1.86	1.85	1.83	1.82	1.81	1.79	1.78	1.77	1.75	1.74	1.73
66.5	2.07	2.05	2.04	2.03	2.01	2.00	1.99	1.97	1.96	1.95	1.94	1.92	1.91	1.90	1.88	1.87	1.86	1.84	1.83	1.82	1.80	1.79	1.78	1.76	1.75
66.9	2.09	2.08	2.06	2.05	2.04	2.02	2.01	2.00	1.98	1.97	1.96	1.94	1.93	1.92	1.90	1.89	1.88	1.86	1.85	1.84	1.82	1.81	1.80	1.78	1.77
67.3	2.11	2.10	2.09	2.07	2.06	2.05	2.03	2.02	2.01	1.99	1.98	1.97	1.95	1.94	1.93	1.91	1.90	1.89	1.87	1.86	1.85	1.83	1.82	1.81	1.79
67.7	2.13	2.12	2.11	2.09	2.08	2.07	2.05	2.04	2.03	2.02	2.00	1.99	1.98	1.96	1.95	1.94	1.92	1.91	1.90	1.88	1.87	1.86	1.84	1.83	1.82
68.1	2.16	2.14	2.13	2.12	2.10	2.09	2.08	2.06	2.05	2.04	2.02	2.01	2.00	1.98	1.97	1.96	1.95	1.93	1.92	1.91	1.89	1.88	1.87	1.85	1.84
68.5	2.18	2.16	2.15	2.14	2.13	2.11	2.10	2.09	2.07	2.06	2.05	2.03	2.02	2.01	1.99	1.98	1.97	1.95	1.94	1.93	1.91	1.90	1.89	1.87	1.86
68.9	2.20	2.19	2.17	2.16	2.15	2.13	2.12	2.11	2.09	2.08	2.07	2.05	2.04	2.03	2.02	2.00	1.99	1.98	1.96	1.95	1.94	1.92	1.91	1.90	1.88
69.3	2.22	2.21	2.20	2.18	2.17	2.16	2.14	2.13	2.12	2.10	2.09	2.08	2.06	2.05	2.04	2.02	2.01	2.00	1.98	1.97	1.96	1.94	1.93	1.92	1.91
69.7	2.24	2.23	2.22	2.21	2.19	2.18	2.17	2.15	2.14	2.13	2.11	2.10	2.09	2.07	2.06	2.05	2.03	2.02	2.01	1.99	1.98	1.97	1.95	1.94	1.93
70.1	2.27	2.25	2.24	2.23	2.21	2.20	2.19	2.17	2.16	2.15	2.13	2.12	2.11	2.10	2.08	2.07	2.06	2.04	2.03	2.02	2.00	1.99	1.98	1.96	1.95
70.5	2.29	2.28	2.26	2.25	2.24	2.22	2.21	2.20	2.18	2.17	2.16	2.14	2.13	2.12	2.10	2.09	2.08	2.06	2.05	2.04	2.02	2.01	2.00	1.98	1.97
70.9	2.31	2.30	2.28	2.27	2.26	2.25	2.23	2.22	2.21	2.19	2.18	2.17	2.15	2.14	2.13	2.11	2.10	2.09	2.07	2.06	2.05	2.03	2.02	2.01	1.99
71.3	2.33	2.32	2.31	2.29	2.28	2.27	2.25	2.24	2.23	2.21	2.20	2.19	2.18	2.16	2.15	2.14	2.12	2.11	2.10	2.08	2.07	2.06	2.04	2.03	2.02
71.7	2.36	2.34	2.33	2.32	2.30	2.29	2.28	2.26	2.25	2.24	2.22	2.21	2.20	2.18	2.17	2.16	2.14	2.13	2.12	2.10	2.09	2.08	2.07	2.05	2.04
72.0	2.38	2.36	2.35	2.34	2.33	2.31	2.30	2.29	2.27	2.26	2.25	2.23	2.22	2.21	2.19	2.18	2.17	2.15	2.14	2.13	2.11	2.10	2.09	2.07	2.06
72.4	2.40	2.39	2.37	2.36	2.35	2.33	2.32	2.31	2.29	2.28	2.27	2.25	2.24	2.23	2.22	2.20	2.19	2.18	2.16	2.15	2.14	2.12	2.11	2.10	2.08
72.8	2.42	2.41	2.40	2.38	2.37	2.36	2.34	2.33	2.32	2.30	2.29	2.28	2.26	2.25	2.24	2.22	2.21	2.20	2.18	2.17	2.16	2.15	2.13	2.12	2.11
73.2	2.44	2.43	2.42	2.40	2.39	2.38	2.37	2.35	2.34	2.33	2.31	2.30	2.29	2.27	2.26	2.25	2.23	2.22	2.21	2.19	2.18	2.17	2.15	2.14	2.13
73.6	2.47	2.45	2.44	2.43	2.41	2.40	2.39	2.37	2.36	2.35	2.33	2.32	2.31	2.30	2.28	2.27	2.26	2.24	2.23	2.22	2.20	2.19	2.18	2.16	2.15
74.0	2.49	2.48	2.46	2.45	2.44	2.42	2.41	2.40	2.38	2.37	2.36	2.34	2.33	2.32	2.30	2.29	2.28	2.26	2.25	2.24	2.22	2.21	2.20	2.18	2.17
74.4	2.51	2.50	2.48	2.47	2.46	2.44	2.43	2.42	2.41	2.39	2.38	2.37	2.35	2.34	2.33	2.31	2.30	2.29	2.27	2.26	2.25	2.23	2.22	2.21	2.19
74.8	2.53	2.52	2.51	2.49	2.48	2.47	2.45	2.44	2.43	2.41	2.40	2.39	2.37	2.36	2.35	2.34	2.32	2.31	2.30	2.28	2.27	2.26	2.24	2.23	2.22

PREDICTION EQUATIONS FOR MVV MALES * 60% OF PREDICTED **

AGE (YEARS)

HEIGHT (IN)	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46
59.1	74.	75.	76.	70.	69.	69.	68.	68.	67.	66.	66.	65.	64.	64.	63.	62.	62.	61.	60.	60.	59.	58.	58.	57.	57.
59.4	75.	76.	77.	71.	70.	70.	69.	69.	68.	67.	67.	66.	65.	65.	64.	63.	63.	62.	61.	61.	60.	59.	59.	58.	58.
59.8	76.	77.	78.	73.	72.	71.	71.	70.	70.	69.	68.	68.	67.	67.	66.	65.	65.	64.	63.	63.	62.	61.	61.	60.	59.
60.2	77.	78.	79.	74.	73.	73.	72.	72.	71.	70.	70.	69.	68.	68.	67.	66.	66.	65.	64.	64.	63.	62.	62.	61.	61.
60.6	78.	79.	80.	75.	74.	74.	73.	73.	72.	71.	71.	70.	69.	69.	68.	67.	67.	66.	65.	65.	64.	63.	63.	62.	62.
61.0	80.	81.	82.	76.	75.	75.	74.	74.	73.	72.	72.	71.	70.	70.	69.	68.	68.	67.	66.	66.	65.	64.	64.	63.	63.
61.4	81.	82.	83.	78.	77.	76.	76.	75.	75.	74.	73.	73.	72.	72.	71.	70.	70.	69.	68.	68.	67.	66.	66.	65.	64.
61.8	82.	83.	84.	79.	78.	78.	77.	77.	76.	75.	75.	74.	73.	73.	72.	71.	71.	70.	69.	69.	68.	67.	67.	66.	66.
62.2	83.	84.	85.	80.	79.	79.	78.	78.	77.	76.	76.	75.	74.	74.	73.	72.	72.	71.	70.	70.	69.	68.	68.	67.	67.
62.6	84.	85.	86.	81.	80.	80.	79.	79.	78.	77.	77.	76.	75.	75.	74.	73.	73.	72.	71.	71.	70.	69.	69.	68.	68.
63.0	85.	86.	87.	83.	82.	81.	81.	80.	80.	79.	78.	78.	77.	77.	76.	75.	75.	74.	73.	73.	72.	71.	71.	70.	69.
63.4	86.	87.	88.	84.	83.	83.	82.	82.	81.	80.	80.	79.	78.	78.	77.	76.	76.	75.	74.	74.	73.	72.	72.	71.	71.
63.8	87.	88.	89.	85.	84.	84.	83.	83.	82.	81.	81.	80.	79.	79.	78.	77.	77.	76.	75.	75.	74.	73.	73.	72.	72.
64.2	88.	89.	90.	86.	85.	85.	84.	84.	83.	82.	82.	81.	80.	80.	79.	78.	78.	77.	76.	76.	75.	74.	74.	73.	73.
64.6	89.	90.	91.	88.	87.	86.	86.	85.	85.	84.	83.	83.	82.	82.	81.	80.	80.	79.	78.	78.	77.	76.	76.	75.	74.
65.0	91.	92.	93.	89.	88.	88.	87.	87.	86.	85.	85.	84.	83.	83.	82.	81.	81.	80.	79.	79.	78.	77.	77.	76.	76.
65.4	92.	93.	94.	90.	89.	89.	88.	88.	87.	86.	86.	85.	84.	84.	83.	82.	82.	81.	80.	80.	79.	78.	78.	77.	77.
65.7	93.	94.	95.	91.	90.	90.	89.	89.	88.	87.	87.	86.	85.	85.	84.	83.	83.	82.	81.	81.	80.	79.	79.	78.	78.
66.1	94.	95.	96.	93.	92.	91.	91.	90.	90.	89.	88.	88.	87.	87.	86.	85.	85.	84.	83.	83.	82.	81.	81.	80.	79.
66.5	95.	96.	97.	94.	93.	92.	92.	91.	91.	90.	89.	89.	88.	88.	87.	86.	86.	85.	84.	84.	83.	82.	82.	81.	80.
66.9	96.	97.	98.	95.	94.	94.	93.	93.	92.	91.	91.	90.	89.	89.	88.	87.	87.	86.	85.	85.	84.	83.	83.	82.	82.
67.3	97.	98.	99.	96.	95.	95.	94.	94.	93.	92.	92.	91.	90.	90.	89.	88.	88.	87.	86.	86.	85.	84.	84.	83.	83.
67.7	98.	99.	100.	98.	97.	96.	96.	95.	95.	94.	93.	93.	92.	92.	91.	90.	90.	89.	88.	88.	87.	86.	86.	85.	84.
68.1	99.	100.	101.	99.	98.	97.	97.	96.	96.	95.	94.	94.	93.	93.	92.	91.	91.	90.	89.	89.	88.	87.	87.	86.	85.
68.5	100.	101.	102.	100.	99.	99.	98.	98.	97.	96.	96.	95.	94.	94.	93.	92.	92.	91.	90.	90.	89.	88.	88.	87.	87.
68.9	102.	103.	104.	101.	100.	100.	99.	99.	98.	97.	97.	96.	95.	95.	94.	93.	93.	92.	91.	91.	90.	89.	89.	88.	88.
69.3	103.	104.	105.	103.	102.	101.	101.	100.	100.	99.	98.	98.	97.	97.	96.	95.	95.	94.	93.	93.	92.	91.	91.	90.	89.
69.7	104.	105.	106.	104.	103.	102.	102.	101.	101.	100.	99.	99.	98.	98.	97.	96.	96.	95.	94.	94.	93.	92.	92.	91.	90.
70.1	105.	106.	107.	105.	104.	104.	103.	103.	102.	101.	101.	100.	99.	99.	98.	97.	97.	96.	95.	95.	94.	93.	93.	92.	92.
70.5	106.	107.	108.	106.	105.	105.	104.	104.	103.	102.	102.	101.	100.	100.	99.	98.	98.	97.	96.	96.	95.	94.	94.	93.	93.
70.9	107.	108.	109.	108.	107.	106.	106.	105.	105.	104.	103.	103.	102.	102.	101.	100.	100.	99.	98.	98.	97.	96.	96.	95.	94.
71.3	108.	109.	110.	109.	108.	107.	107.	106.	106.	105.	104.	104.	103.	103.	102.	101.	101.	100.	99.	99.	98.	97.	97.	96.	95.
71.7	109.	110.	111.	110.	109.	108.	108.	107.	107.	106.	105.	105.	104.	104.	103.	102.	102.	101.	100.	100.	99.	98.	98.	97.	96.
72.0	110.	111.	112.	111.	110.	110.	109.	109.	108.	107.	107.	106.	105.	105.	104.	103.	103.	102.	101.	101.	100.	99.	99.	98.	98.
72.4	111.	112.	113.	113.	112.	111.	111.	110.	110.	109.	108.	108.	107.	107.	106.	105.	105.	104.	103.	103.	102.	101.	101.	100.	99.
72.8	113.	114.	115.	114.	113.	112.	112.	111.	111.	110.	109.	109.	108.	108.	107.	106.	106.	105.	104.	104.	103.	102.	102.	101.	100.
73.2	114.	115.	116.	115.	114.	113.	113.	112.	112.	111.	110.	110.	109.	109.	108.	107.	107.	106.	105.	105.	104.	103.	103.	102.	101.
73.6	115.	116.	117.	116.	115.	115.	114.	114.	113.	112.	112.	111.	110.	110.	109.	108.	108.	107.	106.	106.	105.	104.	104.	103.	103.
74.0	116.	117.	118.	118.	117.	116.	116.	115.	115.	114.	113.	113.	112.	112.	111.	110.	110.	109.	108.	108.	107.	106.	106.	105.	104.
74.4	117.	118.	119.	119.	118.	117.	117.	116.	116.	115.	114.	114.	113.	113.	112.	111.	111.	110.	109.	109.	108.	107.	107.	106.	105.
74.8	118.	119.	120.	120.	119.	118.	118.	117.	117.	116.	115.	115.	114.	114.	113.	112.	112.	111.	110.	110.	109.	108.	108.	107.	106.
75.2	119.	120.	121.	121.	120.	120.	119.	119.	118.	117.	117.	116.	115.	115.	114.	113.	113.	112.	111.	111.	110.	109.	109.	108.	108.
75.6	120.	121.	122.	123.	122.	121.	121.	120.	120.	119.	118.	118.	117.	117.	116.	115.	115.	114.	113.	113.	112.	111.	111.	110.	109.
76.0	121.	122.	123.	124.	123.	122.	122.	121.	121.	120.	119.	119.	118.	118.	117.	116.	116.	115.	114.	114.	113.	112.	112.	111.	110.
76.4	122.	123.	124.	125.	124.	123.	123.	122.	122.	121.	120.	120.	119.	119.	118.	117.	117.	116.	115.	115.	114.	113.	113.	112.	111.
76.8	124.	125.	126.	126.	125.	125.	124.	124.	123.	122.	122.	121.	120.	120.	119.	118.	118.	117.	116.	116.	115.	114.	114.	113.	113.
77.2	125.	126.	127.	128.	127.	126.	126.	125.	125.	124.	123.	123.	122.	122.	121.	120.	120.	119.	118.	118.	117.	116.	116.	115.	114.
77.6	126.	127.	128.	129.	128.	127.	127.	126.	126.	125.	124.	124.	123.	123.	122.	121.	121.	120.	119.	119.	118.	117.	117.	116.	115.
78.0	127.	128.	129.	130.	129.	128.	128.	127.	127.	126.	125.	125.	124.	124.	123.	122.	122.	121.	120.	120.	119.	118.	118.	117.	116.
78.3	128.	129.	130.	131.	130.	129.	129.	128.	128.	127.	126.	126.	125.	125.	124.	123.	123.	122.	121.	121.	120.	119.	119.	118.	117.
78.7	129.	130.	131.	133.	132.	131.	131.	130.	130.	129.	128.	128.	127.	127.	126.	125.	125.	124.	123.	123.	122.	121.	121.	120.	119.
79.1	130.	131.	132.	134.	133.	132.	132.	131.	131.	130.	129.	129.	128.	128.	127.	126.	126.	125.	124.	124.	123.	122.	122.	121.	120.
79.5	131.	132.	133.	135.	134.	133.	133.	132.	132.	131.	130.	130.	129.	129.	128.	127.	127.	126.	125.	125.	124.	123.	123.	122.	121.
79.9	132.	133.	134.	136.	135.	134.	134.	133.	133.	132.	131.	131.	130.	130.	129.	128.	128.	127.	126.	126.	125.	124.	124.	123.	122.
80.3	133.	134.	135.	138.	137.	136.	136.	135.	135.	134.	133.	133.	132.	132.	131.	130.	130.	129.	128.	128.	127.	126.	126.	125.	124.
80.7	135.	136.	137.	139.	138.	137.	137.	136.	136.	135.	134.	134.	133.	133.	132.	131.	131.	130.	129.	129.	128.	127.	127.	126.	125.
81.1	136.	137.	138.	140.	139.	138.	138.	137.	137.	136.	135.	135.	134.	134.	133.	132.	132.	131.	130.	130.	129.	128.	128.	127.	126.
81.5	137.	138.	139.	141.	140.	139.	139.	138.	138.	137.	136.	136.	135.	135.	134.	133.	133.	132.	131.	131.	130.	129.	129.	128.	127.
81.9	138.	139.	140.	143.	142.	141.	141.	140.	140.	139.	138.	138.	137.	137.	136.	135.	135.	134.	133.	133.	132.	131.	131.	130.	129.
82.3	139.	140.	141.	144.	143.	142.	142.	141.	141.	140.	139.	139.	138.	138.	137.	136.	136.	135.	134.	134.	133.	132.	132.	131.	130.
82.7	140.	141.	142.	145.	144.	143.	143.	142.	142.	141.	140.	140.	139.	139.	138.	137.	137.	136.	135.	135.	134.	133.	133.	132.	131.

PREDICTION EQUATIONS FOR MVV — MALES — * 80% OF PREDICTED **

HEIGHT (IN)	AGE (YEARS) 47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71
59.1	56.	55.	55.	54.	53.	53.	52.	51.	51.	50.	49.	49.	48.	47.	47.	46.	46.	45.	44.	44.	43.	42.	42.	41.	40.
59.4	57.	56.	56.	55.	55.	54.	53.	53.	52.	51.	51.	50.	49.	49.	48.	47.	47.	46.	45.	45.	44.	44.	43.	42.	42.
59.8	58.	58.	57.	56.	56.	55.	54.	54.	53.	53.	52.	51.	51.	50.	49.	49.	48.	47.	47.	46.	45.	45.	44.	43.	43.
60.2	60.	59.	58.	58.	57.	56.	56.	55.	54.	54.	53.	52.	52.	51.	51.	50.	49.	49.	48.	47.	47.	46.	45.	45.	44.
60.6	61.	60.	60.	59.	58.	58.	57.	56.	56.	55.	54.	54.	53.	52.	52.	51.	50.	50.	49.	49.	48.	47.	47.	46.	45.
61.0	62.	61.	61.	60.	60.	59.	58.	58.	57.	56.	56.	55.	54.	54.	53.	52.	52.	51.	50.	50.	49.	49.	48.	47.	47.
61.4	63.	63.	62.	61.	61.	60.	59.	59.	58.	58.	57.	56.	56.	55.	54.	54.	53.	52.	52.	51.	50.	50.	49.	48.	48.
61.8	65.	64.	63.	63.	62.	61.	61.	60.	59.	59.	58.	57.	57.	56.	56.	55.	54.	54.	53.	52.	52.	51.	50.	50.	49.
62.2	66.	65.	65.	64.	63.	63.	62.	61.	61.	60.	59.	59.	58.	57.	57.	56.	55.	55.	54.	54.	53.	52.	52.	51.	50.
62.6	67.	66.	66.	65.	65.	64.	63.	63.	62.	61.	61.	60.	59.	59.	58.	57.	57.	56.	55.	55.	54.	53.	53.	52.	52.
63.0	68.	68.	67.	66.	66.	65.	64.	64.	63.	62.	62.	61.	61.	60.	59.	59.	58.	57.	57.	56.	55.	55.	54.	53.	53.
63.4	70.	69.	68.	68.	67.	66.	66.	65.	64.	64.	63.	62.	62.	61.	61.	60.	59.	59.	58.	57.	57.	56.	55.	55.	54.
63.8	71.	70.	70.	69.	68.	68.	67.	66.	66.	65.	64.	64.	63.	62.	62.	61.	60.	60.	59.	59.	58.	57.	57.	56.	55.
64.2	72.	71.	71.	70.	70.	69.	68.	68.	67.	66.	66.	65.	64.	64.	63.	62.	62.	61.	60.	60.	59.	58.	58.	57.	57.
64.6	73.	73.	72.	71.	71.	70.	69.	69.	68.	68.	67.	66.	66.	65.	64.	64.	63.	62.	62.	61.	60.	60.	59.	58.	58.
65.0	75.	74.	73.	73.	72.	71.	71.	70.	69.	69.	68.	67.	67.	66.	66.	65.	64.	64.	63.	62.	62.	61.	60.	60.	59.
65.4	76.	75.	75.	74.	73.	73.	72.	71.	71.	70.	69.	69.	68.	67.	67.	66.	65.	65.	64.	64.	63.	62.	62.	61.	60.
65.7	77.	76.	76.	75.	74.	74.	73.	73.	72.	71.	71.	70.	69.	69.	68.	67.	67.	66.	65.	65.	64.	63.	63.	62.	62.
66.1	78.	78.	77.	76.	76.	75.	74.	74.	73.	73.	72.	71.	71.	70.	69.	69.	68.	67.	67.	66.	65.	65.	64.	63.	63.
66.5	80.	79.	78.	78.	77.	76.	76.	75.	74.	74.	73.	72.	72.	71.	71.	70.	69.	69.	68.	67.	67.	66.	65.	65.	64.
66.9	81.	80.	80.	79.	78.	78.	77.	76.	76.	75.	74.	74.	73.	72.	72.	71.	70.	70.	69.	69.	68.	67.	67.	66.	65.
67.3	82.	81.	81.	80.	79.	79.	78.	78.	77.	76.	76.	75.	74.	74.	73.	72.	72.	71.	70.	70.	69.	68.	68.	67.	67.
67.7	83.	83.	82.	81.	81.	80.	79.	79.	78.	77.	77.	76.	76.	75.	74.	74.	73.	72.	72.	71.	70.	70.	69.	68.	68.
68.1	85.	84.	83.	83.	82.	81.	81.	80.	79.	79.	78.	77.	77.	76.	76.	75.	74.	74.	73.	72.	72.	71.	70.	70.	69.
68.5	86.	85.	85.	84.	83.	83.	82.	81.	81.	80.	79.	79.	78.	77.	77.	76.	75.	75.	74.	74.	73.	72.	72.	71.	70.
68.9	87.	86.	86.	85.	84.	84.	83.	83.	82.	81.	81.	80.	79.	79.	78.	77.	77.	76.	75.	75.	74.	73.	73.	72.	72.
69.3	88.	88.	87.	86.	86.	85.	84.	84.	83.	82.	82.	81.	81.	80.	79.	79.	78.	77.	77.	76.	75.	75.	74.	73.	73.
69.7	90.	89.	88.	88.	87.	86.	86.	85.	84.	84.	83.	82.	82.	81.	80.	80.	79.	79.	78.	77.	77.	76.	75.	75.	74.
70.1	91.	90.	90.	89.	88.	88.	87.	86.	86.	85.	84.	84.	83.	82.	82.	81.	80.	80.	79.	79.	78.	77.	77.	76.	75.
70.5	92.	91.	91.	90.	89.	89.	88.	88.	87.	86.	86.	85.	84.	84.	83.	82.	82.	81.	80.	80.	79.	78.	78.	77.	77.
70.9	93.	93.	92.	91.	91.	90.	89.	89.	88.	87.	87.	86.	86.	85.	84.	84.	83.	82.	82.	81.	80.	80.	79.	78.	78.
71.3	95.	94.	93.	93.	92.	91.	91.	90.	89.	89.	88.	87.	87.	86.	85.	85.	84.	84.	83.	82.	82.	81.	80.	80.	79.
71.7	96.	95.	95.	94.	93.	93.	92.	91.	91.	90.	89.	89.	88.	87.	87.	86.	85.	85.	84.	83.	83.	82.	82.	81.	80.
72.0	97.	96.	96.	95.	94.	94.	93.	93.	92.	91.	91.	90.	89.	89.	88.	87.	87.	86.	85.	85.	84.	83.	83.	82.	82.
72.4	98.	98.	97.	96.	96.	95.	94.	94.	93.	92.	92.	91.	91.	90.	89.	89.	88.	87.	87.	86.	85.	85.	84.	83.	83.
72.8	100.	99.	98.	98.	97.	96.	96.	95.	94.	94.	93.	92.	92.	91.	90.	90.	89.	89.	88.	87.	87.	86.	85.	85.	84.
73.2	101.	100.	100.	99.	98.	98.	97.	96.	96.	95.	94.	94.	93.	92.	92.	91.	90.	90.	89.	88.	88.	87.	87.	86.	85.
73.6	102.	101.	101.	100.	99.	99.	98.	98.	97.	96.	96.	95.	94.	94.	93.	92.	92.	91.	90.	90.	89.	88.	88.	87.	87.
74.0	103.	103.	102.	101.	101.	100.	99.	99.	98.	97.	97.	96.	96.	95.	94.	94.	93.	92.	92.	91.	90.	90.	89.	88.	88.
74.4	105.	104.	103.	102.	102.	101.	101.	100.	99.	99.	98.	97.	97.	96.	95.	95.	94.	94.	93.	92.	92.	91.	90.	90.	89.
74.8	106.	105.	104.	104.	103.	103.	102.	101.	101.	100.	99.	99.	98.	97.	97.	96.	95.	95.	94.	93.	93.	92.	92.	91.	90.
75.2	107.	106.	106.	105.	104.	104.	103.	103.	102.	101.	101.	100.	99.	99.	98.	97.	97.	96.	95.	95.	94.	93.	93.	92.	92.
75.6	108.	108.	107.	106.	106.	105.	104.	104.	103.	102.	102.	101.	101.	100.	99.	99.	98.	97.	97.	96.	95.	95.	94.	93.	93.
76.0	110.	109.	108.	107.	107.	106.	106.	105.	104.	104.	103.	102.	102.	101.	100.	100.	99.	99.	98.	97.	97.	96.	95.	95.	94.
76.4	111.	110.	109.	109.	108.	108.	107.	106.	106.	105.	104.	104.	103.	102.	102.	101.	100.	100.	99.	98.	98.	97.	97.	96.	95.
76.8	112.	111.	111.	110.	109.	109.	108.	107.	107.	106.	105.	105.	104.	104.	103.	102.	102.	101.	100.	100.	99.	98.	98.	97.	97.
77.2	113.	112.	112.	111.	111.	110.	109.	109.	108.	107.	107.	106.	106.	105.	104.	104.	103.	102.	102.	101.	100.	100.	99.	98.	98.
77.6	115.	114.	113.	113.	112.	111.	111.	110.	109.	109.	108.	107.	107.	106.	105.	105.	104.	104.	103.	102.	102.	101.	100.	100.	99.
78.0	116.	115.	114.	114.	113.	113.	112.	111.	111.	110.	109.	109.	108.	107.	107.	106.	105.	105.	104.	103.	103.	102.	102.	101.	100.
78.3	117.	116.	116.	115.	114.	114.	113.	112.	112.	111.	111.	110.	109.	109.	108.	107.	107.	106.	105.	105.	104.	103.	103.	102.	102.
78.7	118.	118.	117.	116.	116.	115.	114.	114.	113.	112.	112.	111.	111.	110.	109.	109.	108.	107.	107.	106.	105.	105.	104.	103.	103.
79.1	120.	119.	118.	118.	117.	116.	116.	115.	114.	114.	113.	112.	112.	111.	110.	110.	109.	109.	108.	107.	107.	106.	105.	105.	104.
79.5	121.	120.	119.	119.	118.	118.	117.	116.	116.	115.	114.	114.	113.	112.	112.	111.	110.	110.	109.	108.	108.	107.	107.	106.	105.
79.9	122.	121.	121.	120.	119.	119.	118.	117.	117.	116.	116.	115.	114.	114.	113.	112.	112.	111.	110.	110.	109.	108.	108.	107.	107.
80.3	123.	123.	122.	121.	121.	120.	119.	119.	118.	117.	117.	116.	116.	115.	114.	114.	113.	112.	112.	111.	110.	110.	109.	108.	108.
80.7	125.	124.	123.	123.	122.	121.	121.	120.	119.	119.	118.	117.	117.	116.	115.	115.	114.	114.	113.	112.	112.	111.	110.	110.	109.
81.1	126.	125.	124.	124.	123.	123.	122.	121.	121.	120.	119.	119.	118.	117.	117.	116.	115.	115.	114.	113.	113.	112.	112.	111.	110.
81.5	127.	126.	126.	125.	124.	124.	123.	122.	122.	121.	121.	120.	119.	119.	118.	117.	117.	116.	115.	115.	114.	113.	113.	112.	111.
81.9	128.	128.	127.	126.	126.	125.	124.	124.	123.	122.	122.	121.	121.	120.	119.	119.	118.	117.	117.	116.	115.	115.	114.	113.	113.
82.3	130.	129.	128.	128.	127.	126.	126.	125.	124.	124.	123.	122.	122.	121.	120.	120.	119.	119.	118.	117.	117.	116.	115.	115.	114.
82.7	131.	130.	129.	129.	128.	128.	127.	126.	126.	125.	124.	124.	123.	122.	122.	121.	120.	120.	119.	118.	118.	117.	116.	116.	115.

PREDICTION EQUATIONS FOR MVV FEMALES * 60% OF PREDICTED **

AGE (YEARS)

HEIGHT (IN)	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46
51.2	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	45.	44.	44.	43.	43.	42.
51.6	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	45.	44.	44.	43.	43.
52.0	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	45.	44.	44.	43.
52.4	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	45.	44.	44.
52.8	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	45.
53.1	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.
53.5	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	46.
53.9	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	48.	47.	47.
54.3	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	48.	47.
54.7	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	48.
55.1	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	50.	50.	49.	49.	48.
55.5	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.
55.9	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.
56.3	63.	62.	62.	61.	61.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.
56.7	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.
57.1	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.
57.5	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.
57.9	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.
58.3	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.
58.7	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.
59.1	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.
59.4	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.
59.8	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.
60.2	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.
60.6	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.
61.0	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.
61.4	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.
61.8	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	59.
62.2	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.
62.6	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.
63.0	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.
63.4	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	62.
63.8	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.
64.2	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.
64.6	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	64.
65.0	77.	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.
65.4	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	65.
65.7	78.	78.	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	66.
66.1	79.	78.	78.	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.
66.5	79.	79.	78.	78.	77.	77.	76.	76.	75.	75.	74.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	67.
66.9	80.	80.	79.	79.	78.	77.	77.	76.	76.	75.	75.	74.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.
67.3	81.	80.	80.	79.	79.	78.	78.	77.	77.	76.	76.	75.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.
67.7	81.	81.	80.	80.	79.	79.	78.	78.	77.	77.	76.	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	69.
68.1	82.	81.	81.	80.	80.	79.	79.	78.	78.	77.	77.	76.	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.
68.5	83.	82.	82.	81.	81.	80.	80.	79.	79.	78.	78.	77.	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.
68.9	83.	83.	82.	82.	81.	81.	80.	80.	79.	79.	78.	78.	78.	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	72.	71.
69.3	84.	83.	83.	82.	82.	81.	81.	80.	80.	79.	79.	78.	78.	78.	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	72.
69.7	85.	84.	84.	83.	83.	82.	82.	81.	81.	80.	80.	79.	79.	79.	78.	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.
70.1	85.	85.	84.	84.	83.	83.	82.	82.	81.	81.	80.	80.	80.	79.	79.	78.	78.	77.	77.	76.	76.	75.	75.	74.	73.
70.5	86.	85.	85.	84.	84.	83.	83.	82.	82.	81.	81.	80.	80.	80.	79.	79.	78.	78.	77.	77.	76.	76.	75.	75.	74.
70.9	86.	86.	85.	85.	84.	84.	83.	83.	82.	82.	81.	81.	81.	80.	80.	79.	79.	78.	78.	77.	77.	76.	76.	75.	74.
71.3	87.	87.	86.	86.	85.	85.	84.	84.	83.	83.	82.	82.	82.	81.	81.	80.	80.	79.	79.	78.	78.	77.	77.	76.	75.
71.7	88.	87.	87.	86.	86.	85.	85.	84.	84.	83.	83.	82.	82.	82.	81.	81.	80.	80.	79.	79.	78.	78.	77.	77.	76.
72.0	88.	88.	87.	87.	86.	86.	85.	85.	84.	84.	83.	83.	83.	83.	82.	82.	81.	81.	80.	80.	79.	79.	78.	78.	77.
72.4	89.	89.	88.	88.	87.	87.	86.	86.	85.	85.	84.	84.	84.	83.	83.	82.	82.	81.	81.	80.	80.	79.	79.	78.	77.
72.8	90.	89.	89.	88.	88.	87.	87.	86.	86.	85.	85.	84.	84.	84.	83.	83.	82.	82.	81.	81.	80.	80.	79.	79.	78.
73.2	90.	90.	89.	89.	88.	88.	87.	87.	86.	86.	85.	85.	85.	84.	84.	83.	83.	82.	82.	81.	81.	80.	80.	79.	78.
73.6	91.	91.	90.	90.	89.	89.	88.	88.	87.	87.	86.	85.	85.	85.	84.	84.	83.	83.	82.	82.	81.	81.	80.	80.	79.
74.0	92.	91.	91.	90.	90.	89.	89.	88.	88.	87.	87.	86.	86.	86.	85.	85.	84.	84.	83.	83.	82.	82.	81.	81.	80.
74.4	93.	92.	92.	91.	91.	90.	90.	89.	89.	88.	88.	87.	87.	86.	86.	85.	85.	84.	84.	83.	83.	82.	82.	81.	80.
74.8	93.	93.	92.	91.	91.	90.	90.	89.	89.	88.	88.	87.	87.	87.	86.	86.	85.	85.	84.	84.	83.	83.	82.	81.	81.

PREDICTION EQUATIONS FOR [illegible] FEMALES [illegible]

AGE (YEARS)

HEIGHT (in)	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71
51.2	41.	41.	40.	40.	39.	39.	38.	38.	37.	37.	36.	36.	35.	35.	34.	34.	33.	33.	32.	32.	31.	31.	30.	30.	29.
51.6	42.	42.	41.	41.	40.	40.	39.	39.	38.	38.	37.	37.	36.	36.	35.	35.	34.	34.	33.	33.	32.	32.	31.	31.	30.
52.0	43.	42.	42.	41.	41.	40.	40.	39.	39.	38.	38.	37.	36.	36.	35.	35.	34.	34.	33.	33.	32.	32.	31.	31.	30.
52.4	43.	43.	42.	42.	41.	41.	40.	39.	39.	38.	38.	37.	37.	36.	36.	35.	35.	34.	34.	33.	33.	32.	31.	31.	30.
52.8	44.	44.	43.	43.	42.	42.	41.	40.	40.	39.	39.	38.	38.	37.	37.	36.	36.	35.	35.	34.	34.	33.	33.	32.	31.
53.1	45.	44.	44.	43.	43.	42.	42.	41.	41.	40.	40.	39.	39.	38.	38.	37.	37.	36.	36.	35.	35.	34.	33.	32.	32.
53.5	45.	45.	44.	44.	43.	43.	42.	42.	41.	40.	40.	39.	39.	38.	38.	37.	37.	36.	35.	35.	34.	34.	33.	32.	32.
53.9	46.	46.	45.	45.	44.	44.	43.	43.	42.	41.	41.	40.	39.	39.	38.	38.	37.	37.	36.	36.	35.	35.	34.	34.	33.
54.3	47.	46.	46.	45.	45.	44.	43.	43.	42.	41.	41.	40.	40.	39.	39.	38.	38.	37.	37.	36.	36.	35.	35.	34.	33.
54.7	47.	47.	46.	46.	45.	45.	44.	44.	43.	43.	42.	41.	41.	40.	40.	39.	39.	38.	38.	37.	37.	36.	36.	35.	34.
55.1	48.	47.	47.	46.	46.	45.	45.	44.	44.	43.	42.	42.	41.	41.	40.	40.	39.	39.	38.	38.	37.	37.	36.	36.	35.
55.5	49.	48.	48.	47.	47.	46.	46.	45.	45.	44.	43.	42.	42.	41.	41.	40.	40.	39.	39.	38.	38.	37.	37.	36.	35.
55.9	49.	49.	48.	48.	47.	47.	46.	46.	45.	44.	44.	43.	43.	42.	42.	41.	41.	40.	40.	39.	39.	38.	37.	37.	36.
56.3	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	45.	44.	43.	43.	42.	42.	41.	41.	40.	40.	39.	39.	38.	37.	37.
56.7	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	45.	45.	44.	44.	43.	43.	42.	42.	41.	40.	40.	39.	39.	38.	38.
57.1	51.	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	45.	45.	44.	44.	43.	43.	42.	42.	41.	41.	40.	39.	39.	38.
57.5	52.	51.	51.	50.	50.	49.	49.	48.	48.	47.	46.	46.	45.	45.	44.	44.	43.	43.	42.	41.	41.	40.	40.	39.	39.
57.9	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	47.	47.	46.	46.	45.	45.	44.	44.	43.	42.	42.	41.	41.	40.	39.
58.3	54.	53.	53.	52.	51.	51.	50.	50.	49.	49.	48.	47.	47.	46.	46.	45.	45.	44.	44.	43.	43.	42.	41.	41.	40.
58.7	54.	54.	53.	53.	52.	52.	51.	51.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	45.	44.	44.	43.	43.	42.	41.
59.1	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	45.	44.	44.	43.	42.	42.
59.4	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	45.	44.	43.	43.	42.
59.8	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	45.	44.	44.	43.
60.2	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	45.	44.	43.
60.6	57.	57.	56.	56.	55.	55.	54.	54.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	44.
61.0	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	46.	45.	44.
61.4	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	51.	51.	50.	50.	49.	49.	48.	48.	47.	47.	46.	45.
61.8	59.	58.	58.	57.	57.	56.	56.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.	47.	47.	46.	46.
62.2	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	48.	48.	47.	46.
62.6	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	49.	49.	48.	47.
63.0	61.	60.	60.	59.	59.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	51.	50.	50.	49.	49.	48.
63.4	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	50.	50.	49.
63.8	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	50.	49.
64.2	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.	50.
64.6	64.	63.	63.	62.	62.	61.	61.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	53.	52.	52.	51.
65.0	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	52.	52.	51.
65.4	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	54.	53.	52.
65.7	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	55.	54.	53.	52.
66.1	66.	66.	65.	65.	64.	64.	63.	63.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	56.	55.	54.	54.	53.
66.5	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	55.	54.	54.
66.9	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	57.	56.	55.	55.
67.3	68.	68.	67.	67.	66.	66.	65.	65.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	59.	58.	58.	57.	56.	56.	55.
67.7	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	59.	59.	58.	57.	57.	56.	55.
68.1	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	58.	57.	57.	56.
68.5	70.	70.	69.	69.	68.	68.	67.	67.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.	58.	58.	57.
68.9	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	59.	59.	58.
69.3	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	60.	59.
69.7	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.	59.
70.1	73.	73.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	64.	64.	63.	63.	62.	62.	61.	61.	60.
70.5	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	63.	62.	61.
70.9	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	62.	61.
71.3	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	64.	63.	62.
71.7	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	63.	62.
72.0	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	66.	65.	65.	64.	63.
72.4	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	65.	65.	64.	63.
72.8	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	67.	66.	65.	64.
73.2	78.	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	66.	65.	64.
73.6	78.	78.	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	68.	67.	66.	65.
74.0	79.	79.	78.	78.	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.	67.	66.
74.4	80.	79.	79.	78.	78.	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	68.	67.	67.
74.8	80.	80.	79.	79.	78.	78.	77.	77.	76.	76.	75.	75.	74.	74.	73.	73.	72.	72.	71.	71.	70.	70.	69.	69.	68.

Appendix C to Part 718—Blood-Gas Tables

The following tables set forth the values to be applied in determining whether total disability may be established in accordance with §§718.204(c)(2) and 718.305 (a), (c). The values contained in the tables are indicative of impairment only. They do not establish a degree of disability except as provided in §§718.204(c)(2) and 718.305 (a), (c) of this subchapter, nor do they establish standards for determining normal alveolar gas exchange values for any particular individual.

A miner who meets the following medical specifications shall be found to be totally disabled, in the absence of rebutting evidence, if the values specified in one of the following tables are met:

(1) For arterial blood-gas studies performed at test sites up to 2,999 feet above sea level:

Arterial $_pCO_2$ (mm Hg)	Arterial $_pO_2$ equal to or less than (mm Hg)
25 or below	75
26	74
27	73
28	72
29	71
30	70
31	69
32	68
33	67
34	66
35	65
36	64
37	63
38	62
39	61
40–49	60
Above 50	([1])

[1] Any value.

(2) For arterial blood-gas studies performed at test sites 3,000 to 5,999 feet above sea level:

Arterial $_pCO_2$ (mm Hg)	Arterial $_pO_2$ equal to or less than (mm Hg)
25 or below	70
26	69
27	68
28	67
29	66
30	65
31	64
32	63
33	62
34	61
35	60
36	59
37	58
38	57
39	56
40–49	55
Above 50	([2])

[2] Any value.

(3) For arterial blood-gas studies performed at test sites 6,000 feet or more above sea level:

Arterial $_pCO_2$ (mm Hg)	Arterial $_pO_2$ equal to or less than (mm Hg)
25 or below	65
26	64
27	63
28	62
29	61
30	60
31	59
32	58
33	57
34	56
35	55
36	54
37	53
38	52
39	51
40–49	50
Above 50	([3])

[3] Any value.

PART 722—CRITERIA FOR DETERMINING WHETHER STATE WORKMEN'S COMPENSATION LAWS PROVIDE ADEQUATE COVERAGE FOR PNEUMOCONIOSIS AND LISTING OF APPROVED STATE LAWS

Introductory

Sec.
722.101 Purpose and scope of this part.
722.102 Definitions and use of terms.

Procedure for Determining Whether a State Law Provides Adequate Coverage for Pneumoconiosis

722.103 Application to the Secretary.
722.104 Contents of application, supporting documents.
722.105 Initial action on the request.

Criteria: Standards of Coverage, Eligibility

722.110 Coverage generally.
722.111 Miner.
722.112 Widow, surviving divorced wife.
722.113 Child.
722.114 Parents, brothers, or sisters.

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Cases of Alleged Asbestos-Related Disease: a Radiologic Re-Evaluation

R. B. Reger, PhD; W. S. Cole, MD; E. N. Sargent, MD; and P. S. Wheeler, MD

Chest radiographs were re-evaluated from 439 active and retired tireworkers previously designated as having a condition consistent with an asbestiform mineral exposure. The review was performed in an independent manner by three board-certified radiologists according to guidelines from an international classification system. The percentage of cases with abnormalities consistent with an asbestiform mineral exposure found separately by the three radiologists was 3.7, 3.0, and 2.7%. Application of an algorithm to form a consensus evaluation indicated that approximately 3.6% (16) of the subjects evaluated may have a condition consistent with an asbestos exposure. A more detailed review, however, revealed that only 11 workers, or 2.5% of the total, would have a reasonable likelihood of having such a condition. Most cases were normal and the majority of abnormalities present on the radiographs evaluated were nonoccupational in origin. Prevelent conditions identified included healed tuberculosis, histoplasmosis, emphysema, discoid atelectasis, effusions, healed rib fractures, scarring due to infection or old inflammatory disease, possible cancer, miscellaneous nonspecific linear markings consistent with cigarette smoking and aging, and heart and vascular system diseases—the latter evidenced by an abnormally large number of subjects with healed coronary artery bypass surgery and pacemaker implants. In summary, the best estimate from this study indicates that possibly 16 (3.6%), but more realistically 11 (2.5%), of the 439 tireworkers evaluated may have a condition consistent with exposure to an asbestiform mineral. This represents a 40-fold difference between the re-evaluation results and the original survey work.

Surveillance associated with workers known or suspected of being exposed to asbestos and other fibrous minerals is widespread. In diagnosing asbestos-related diseases (in life), the most important medical tool is the chest radiograph. The presence of irregular or linear opacities (especially in the lung bases) and/or the presence of circumscribed or diffuse pleural thickening on the chest walls or diaphragms (especially bilateral) are generally thought to be consistent with an asbestiform mineral exposure. There are, however, several conditions that can mimic asbestos-related diseases.[1] In addition, pleural changes are often misdiagnosed and the shadows seen may be either fat or muscle shadows, scarring adjacent to old disease, or the result of trauma.[2]

During 1986, 700 to 750 tireworkers at one specific site submitted to medical screening procedures. The procedures involved spirometric testing (with and without a bronchodilator), the administration of a questionnaire on pulmonary symptoms, a cigarette smoking history, a brief occupational history, and the taking of posterior-anterior and left and right oblique radiographs of the chest. Approximately 440 of the patients examined filed legal claims for an asbestos-related injury; therefore, a diagnosis consistent with such filing existed for the subjects. This represents a disease prevalence of nearly 60%. If this was a true generalizable prevalence, it would constitute an epidemic of massive proportions with staggering public and occupational health implications. For each of the subjects with an asbestos-related condition who filed legal claims, the original diagnosis was made by using only the posterior-anterior and oblique chest films, coupled of course with a history of at least potential exposure to asbestos and/or talc. Thus, the purpose of this study was to confirm or refute, although in a select group of enrollees, previous radiologic findings that suggested an unusually high prevalence rate of asbestos-related conditions.

Methods

Posterior-anterior and right and left oblique views of the chest of 439 active and retired tireworkers were

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This work was presented in part at the World Conference on Lung Health, Boston, Mass, May, 1990.

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obtained for evaluation. Identification and other information on the films included subject name, age, and survey number. Three interpreters were used in these trials inasmuch as variability in radiographic evaluations is well documented and an odd number is preferable to resolve discrepancies.[3-6] To reach a final determination on a given case, a median reading of profusion of small opacities was used, thereby not giving undue weight to unusually high or low interpretations. For pleural changes, a consensus (at least two out of three in agreement) was used. All interpreters were initially given no information regarding the films in the set and thus were "blinded" to the purpose of the work in which they were engaged. The physicians participating in these trials were board-certified in radiology, "B" readers,[7] and members of the American College of Radiology Task Force on the Pneumoconioses. The interpretations were provided in an independent manner, without consultations between radiologists. Standard 1980 International Labour Office (ILO) reference radiographs[8] were available for use as needed. The importance of following specific instructions outlined in the ILO system[8] was emphasized and reinforced. These extremely important instructions demand that the radiologist perform more than just mere classification of shadows and also interpret what is seen. In addition, during the interpretation process, each radiologist was assigned an assistant to record observations; the assistant was specially trained and intimately familiar with the 1980 ILO classification system and the use of standardized reporting forms. The posterior-anterior views for subjects were reviewed in a routine manner with the oblique views used at the decision of the radiologist. Bright lighting was used at the discretion of the radiologist; this use varied depending on individual assessment of the technical quality of the radiographs.

Technical Quality

Inasmuch as the technical quality of the radiograph can dramatically influence the diagnoses given,[9,10] a general assessment of film quality is important. Most films in these trials were graded as either good or with technical defects unlikely to impair the classification, whereas a minority were considered of poor quality or unacceptable. One of the radiologists was not as charitable as the others and considered 35 films, (8%) to be unreadable. Common technical problems on some films involved one or more of the following: overexposure, underexposure, fogging, poor contrast, grid lines, poor processing, and inadequate inspiration.

Results

From the data in the Table, 16 (3.6%) of the 439 subjects evaluated have conditions (by consensus) that may be consistent with an asbestos exposure. However, at least five of these 16 cases may be seriously questioned because the exact rules for consensus evaluations

TABLE
Consensus Interpretations

Item	No. of Subjects	%
Normal	265	60.4
Conditions of a nonoccupational origin	158	36.0
Parenchymal abnormalities, median profusion > 0/1	7	1.6
Pleural abnormalities, two out of three radiologists in agreement	8	1.8
Both parenchymal and pleural changes	1	0.2
Total	439	100.0

specified in the "Methods" section were applied loosely, allowing for a worst case scenario. If the five nonexact consensus cases are removed from the tabulation, one is left with 11 (2.5%) of the total number of subjects evaluated with a high likelihood of having a condition consistent with exposure to an asbestiform mineral.

It is interesting that the prevalence of likely asbestos-related conditions noted separately by the three radiologists were similar: 3.7, 3.0, and 2.7%. These percentages do not represent subjects in three mutually exclusive sets; hence, the percentages are not additive. In fact, a great deal of overlap exists representing good agreement in interpretation. A large proportion of the cases re-evaluated had what might be considered as completely normal chests for their ages. Also, the vast majority of abnormalities found were nonoccupational in origin and consisted of conditions one might expect in an aged population. Prevalent nonoccupationally related conditions included healed tuberculosis, histoplasmosis, emphysema, discoid atelectasis, effusions, healed rib fractures, scarring due to infection or old inflammatory disease, possible cancer, miscellaneous nonspecific linear markings consistent with cigarette smoking and aging, and heart and vascular system diseases. The best estimate from these results is that possibly 16, but more realistically 11, of the 439 cases evaluated may have a condition consistent with exposure to an asbestiform mineral.

Discussion

Like previous works[11,12] the present study was prompted by the reporting of exceedingly high rates of alleged asbestos-related disease among rubber workers.

Of 700 to 750 active and retired tireworkers, 439 were considered (initially) to have conditions consistent with exposure to an asbestiform mineral and filed legal claims for an asbestos-related injury. The chest film was the diagnostic aid of paramount importance in the screening procedure, and fortunately the chest films for these cases were available for re-evaluation. The cases were independently re-evaluated by three board-certified radiologists using criteria specified by the ILO classification system relating to dust-induced diseases. The cases re-evaluated were from a select group with an average age of 60.3. More than 90% of the group for which an age was recorded were 50 years of age or older; thus one can expect a host of conditions to exist on the chest films, ie, conditions affecting most any segment of the population over 50.

An interesting (and missing) part of the evaluation would have been to include the cases originally considered negative for asbestos-related disease. This was not possible due to administrative necessities and time constraints. Furthermore, the chest radiograph was only one of the diagnostic aids used in classifying subjects as to whether or not they might have an asbestos-related condition. Nevertheless, of the diagnostic procedures used, chest radiography is the only one that can essentially stand alone in making a diagnosis of a condition consistent with an exposure to asbestos or other fibrous material, ie, given an appropriate exposure history.

At the present time, it is unclear if the highly elevated prevalence of alleged asbestos-related disease reported initially by others at this one particular site is a pattern repeated at other sites in the United States. Nevertheless, the data from this re-evaluation study suggest that the prevalence of disease noted is mistakenly high. A review of the 439 subjects initially deemed positive for asbestos-related disease shows only 16, and more realistically 11 (2.5%), as having conditions consistent with exposure to an asbestiform mineral. It is possible that even the 2.5% prevalence is overstated. For example, many of the subjects were classified as category 1/0, representing only minimal changes which could be the consequence of cigarette smoking, aging, or crowding of the vascularity in the lung bases due to poor inspiration. Moreover, these opacities could be the result of other conditions that mimic asbestosis. The remaining subjects had completely normal chests or indications of a variety of nonoccupational conditions that affect the general population. Thus, the estimate of possible asbestos-related disease we obtained in the re-evaluation trials is 40-fold lower than results from the original survey work.

In summary, the overall prevalence of asbestos-related or other occupationally induced conditions in the sample re-evaluated is not of epidemic proportions and widespread alarm is unwarranted. Ordinary medical and environmental surveillance is recommended.

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MEMORANDUM

TO: Manville Trustees

FROM: Patricia G. Houser, Executive Director

DATE: May 13, 1998

RE: Meeting with the SCB

This Memorandum was composed prior to my receipt of Elihu Inselbuch's letter and memo, which was faxed to me within the last couple of hours. I anticipated that he might not send any such memo and wished to articulate what I believe will be the main arguments the SCB will present against the 100% x-ray submission policy approved the Trustees several months ago, a description of which was presented to the SCB last month.

He argues for a very limited application of medical audit results, and my only response to his memo is to ask you to review, once again, the chart attached hereto, showing the 1st Quarter 1998 Claims, by Most Frequently Used Doctor. His singling out of Drs. Mitchell, Kuebler and Harron does not address the main argument – that "Dr. Bogus" is sufficiently prevalent in sufficient numbers that the difference between a "Dr. Bogus" program and 100% x-ray submission program is not worth the administrative time, resources and risks to even attempt. Those arguments are further fleshed out below.

In the course of Tuesday's discussion, I still believe the following arguments will be made:

1. The TDP only gives the right to audit for the medical reliability of physicians and medical facilities. Therefore, the only allowed use of medical audit is for the Trust to identify and ban unreliable ("Dr. Bogus") physicians and facilities. Applying medical audit results to individual claims is inappropriate for that reason, as well as because the tremendous inter-reader variation, as identified and criticized by the Trust's own study means that individual results from the medical audit program are the pure luck of the draw on who the Trust B-readers are.

2. The Trust does not have the right to ask for x-rays on all Trust non-malignancy claims. That was part of the original Claims Resolution Procedures and was not contemplated as a part of the re-negotiated TDP. The Class Counsel intended that the matrix system be a "rough justice" system, and requiring and reading x-rays on every single claim violates the spirit and the letter of that concept.

3. The requirement of x-rays is impractical and burdensome for both the Trust and the plaintiffs' bar, threatening the security of the underlying evidence critical to that claimant's lawsuits against other co-defendants.

4. Any so-called financial adjustment or savings realized by downgrades as a result of the Trust B-readings is ephemeral, and will inevitably be more than eaten up by ADR and litigation costs as all the downgrades are pushed through ADR and, if necessary, into the courts.

What follows are responses to the specific arguments raised above. At the last Trustee meeting we agreed that the purpose of Tuesday's meeting is to listen to the SCB's comments and their counter-proposals, if any, and that this is not a forum for us to have to negotiate, justify or defend the Trust's position. Please avail yourselves the opportunity to first talk among yourselves concerns you have, if any, regarding any point raised by the SCB. The staff would appreciate the opportunity to address those concerns with you *before* you respond to the SCB in any formal or informal way, or even give them any indication that you are prepared to compromise from the Trust's current position, since that will immediately establish a new floor from which the SCB will negotiate.

Argument: The TDP only gives the right to audit for "Dr. Bogus," and does not allow individual audit results to be applied to individual claims.

While TDP Section C.8, which authorizes the Trust to perform medical audits, provides that audits can be used to measure the reliability of doctors and medical facilities, it does not limit the audits solely to those purposes. The first sentence of that Section states: "[I]**n all cases**" the Trust may require that medical evidence comply with recognized medical standards "**to assure that such evidence is reliable.**" The Section adds that the Trust may develop methods for auditing the reliability of medical evidence, including independent reading of x-rays. This portion of C.8 permits the Trust to perform medical audits to assure itself that the medical evidence is reliable in **all** cases that it chooses to audit. What this clause provides, simply, is that the Trust is entitled to assure itself that evidence is reliable before it offers to pay that claim.

Further, the Trust Agreement specifies as a purpose of the Trust the use of Trust assets "to deliver fair, adequate and equitable compensation to ***bona fide*** Beneficiaries ... without overpaying or underpaying any claims ...." Trust Agreement Section 2.02(i). This implies that examining claims critically to determine which are bona fide and to avoid overpaying less deserving claims is not only within the Trust's authority, it is among the Trust's basic duties.

In sum, it is the Trust's duty to sort out *bona fide* from non-*bona fide* claims. The Trust documents, and particularly the TDP, must be interpreted in a manner that enables the Trust to accomplish this basic duty. The TDP specifically authorizes the Trust to require that medical evidence comply with recognized medical standards "in every case" to assure the Trust that the evidence is reliable, and it further authorizes the Trust to develop audits to test the reliability of medical evidence. It is reasonable to interpret this as authority to audit the reliability of medical evidence submitted for individual claims, and to act on the results of these audits on an individual case basis. The Trust applies this interpretation of the TDP to downgrade claims that fail medical audit.

Argument: The Trust's own B-reader study concludes that the results of an individual claimant's medical audit are pure luck, based on the identity of the Trust's B-reader, and therefore those results should not be applied to an individual claim.

The Trust has always acknowledged, as has the SCB, that there is substantial variation among B-readers in the interpretation of the presence and/or severity of interstitial fibrosis. The program is structured both to mitigate against a result unfavorable to the claimant, and to provide multiple avenues of appeal of such a result.[1] B-readings provide x-ray data which is recognized by the American Thoracic Society as critically important to the diagnosis of asbestosis, and is therefore used by the Trust to assess the reliability and validity of a claimant's diagnosis.[2]

In most cases, the audit consists of a review of the claimant's x-ray by one or more independent B-readers. The Trust has retained six National Institute for Occupational Safety and Health (NIOSH) certified roentgenographic interpreting physicians (B-readers), to assist it in determining the reliability of a physician's diagnosis of a claim based on a review of the claimant's x-ray. A B-reader designation denotes the highest certification available for physicians trained in the use of the International Labour Office (ILO) system for classifying x-rays for the presence of dust-related lung conditions known as pneumoconiosis. It requires an applicant to pass the NIOSH proficiency examination for classifying chest x-rays for pneumoconiosis (including asbestos-related conditions). As part of the medical audit B-reader selection process, the Trust conferred with counsel who regularly represent asbestos claimants. None of the B-readers selected have testified on behalf of an asbestos defendant.

Experts, of course, can disagree. However, as implemented, the Medical Audit Program is fundamentally fair. It is grounded on established medical standards and predicated upon the judgments of experienced medical experts who have been certified at the highest level of competence in their field. Most importantly, all presumptions lie in favor of the findings made by the claimant's diagnosing doctor(s)' findings, since a claim will not be "downgraded" or "denied" following x-ray audit unless the findings of *two* independent B-readers fail to support the level of disease documented in the claimant's file. And, even those claimants whose claims are downgraded or denied following medical audit are not without further remedy. They can submit new x-rays or other medical evidence and their claims will be re-evaluated and, where merited, re-categorized. Or they can opt to challenge the Trust's actions in arbitration. Pursuant to the agreed upon ADR procedures, at arbitration, the

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1 The fairness of the Trust's program is further demonstrated by the fact that, in the interest of settling claims, the Trust compensates claimants for Category II (non-disabling asbestosis) and Category III (disabling asbestosis) based on a single medical audit B-reader's ability to corroborate what under the ATS standards for the diagnosis of asbestosis is a "sub-diagnostic" profusion level of interstitial opacities. Stated otherwise, the Trust will only deny such a claim where neither of two independent medical audit B-readers are able to corroborate a sub-diagnostic 1/0 profusion of bilateral interstitial lung disease.

2 Both plaintiffs and defendants regularly rely on B-readings to prosecute and defend their asbestos personal injury cases. In addition, as currently crafted, both the Fibreboard and Celotex Trusts require that claimants submit B-readings to establish their claims.

arbitrator, the claimant or the Trust may request independent medical evaluation of the disputed medical evidence by a member of a designated Panel of Independent Medical Experts. The very fact that the ADR Procedures provide for such an independent medical review suggests that the results of that and all prior independent medical audits can, and in fact should, be considered in determining the appropriate categorization of the claim.

Thus, as set forth below, it is simply not the case that medical audit of claimants' x-rays or use of those results was not contemplated by the settlement or provided for by the TDP. The medical audit procedures that have been implemented by the Trust to date and which the Trust proposes be applied in the future are both fair and reasonable. Specifically, the new 100% x-ray review program, where all claimants will be treated alike, enhances the program's fundamental fairness. Thus, whatever the variability of B-reading, all presumptions underlying the Trust's medical audit program lie in favor of the claimant. There can be no question that the Medical Audit Program is necessary to help ensure that the Trust meets its mandate to pay only ***bona fide*** claimants.

Argument: The Trust does not have the right to require x-rays on all Trust non-malignancy claims.

The terms of the TDP and the CRP with respect to x-ray review are consistent. Both documents contemplate the submission of x-rays. The basis for the Trust's right to require that x-rays be submitted and audited "in all cases" under the TDP has been fully set forth above. The CRP Mandatory Claim Form Provisions paragraph I.8. provides, "[w]here a non-malignant asbestos disease is claimed, the claimant must provide with the claim form: (a) posterior-anterior, lateral and oblique chest x-rays, if any, . . . "

The Claims Resolution Procedures ("CRP") is the predecessor to the TDP. The CRP is incorporated by reference in the TDP. Pursuant to the Stipulation of Settlement of the Parties, any inconsistency between the provisions of the Stipulation (and any exhibit thereto) and of the Plan (and any exhibit thereto) shall be resolved in favor of the provisions of the Stipulation of Settlement. The Stipulation of Settlement further provides, the settlement rights of Trust Beneficiaries against the Trust effected by the Stipulation does not otherwise affect any provision of the Plan or any document entered into in connection therewith, including the CRP.

Argument: Requiring x-rays for all non-malignancy claims is impractical and burdensome for both the Trust and the plaintiff's bar, threatening the physical security of the underlying evidence critical to that claimant's lawsuits against other co-defendants.

The x-ray review policy, as compared to a doctor-based audit <u>and</u> the present system will:

- Shorten the time from POC receipt to eligible for offer, thereby speeding compensation to claimants

- Simplify processing for the law firms, utilizing only streamlined processes, one for malignancies and one for non-malignancies
- More efficient for the Trust – one main processing flow without the special handling and time and resource consumption associated with random sampling and reporting
- Treats all claimants the same regardless of representation or diagnosing physician

Regardless of the specifics of the design of the medical audit program, the Trust has determined it is necessary to:

- Hire additional B-readers
- Re-designing x-ray tracking and reporting

These measures will provide more than adequate mechanisms to assure prompt and secure handling of x-rays. Under the new program, we are committed to an average return of x-rays to law firms within 120 days of receipt of a perfected claim file.

Finally, even if the Trust were to use the medical audit program solely to identify unreliable physicians or facilities, and act on that information, the current results of medical audit show that:

- A small number of doctors overwhelmingly dominate the claims filed since 1995, and their medical audit results generally establish a track record of a less than 60% rate of agreement. *[NOTE: The SCB believe that the benchmark rate should be far less than 60%, arguing that an "average" rate should be more than adequate. Of course, the "average" aggregate rate is heavily weighted by the mass screening doctors. The Trustees have given every indication that an agreement rate less than 60% is, by definition, unreliable. In order to significantly reduce the numbers of claims affected, the benchmark rate would have to fall below 40%.]*
- Outright rejection of those physicians' reports would require massive numbers of claimants to be re-examined, resulting in inordinate expense and delay both for the claimant and the Trust, since those claims would have to be re-categorized and re-audited.
- Assuming a benchmark rate in the 50% to 60% range, the difference in requiring x-rays for claimants represented only by those physicians and for *all* claimants is minimal.
- Making x-ray submission a universal requirement simplifies and speeds the process up for all claimants, is far more efficient and levels the playing field for all claimants. In short, it is fair.

Argument: Any adjustment or savings realized by medical audit downgrades will be more than consumed by ADR and litigation costs as downgraded claims are pushed through ADR and, if necessary, into the Courts.

At the most recent meeting of the SCB regarding the proposed 100% x-ray submission policy, the Trust estimated the pre- versus post-x-ray-review category of the current unsettled population of non-malignancy claims based on very conservative assumptions. The population of 2,200 that went into the creation of the matrix was the claims which had been randomly selected for medical audit during the previous four quarters (plus the Futures Liability Sample study), which had been originally categorized as 1, 2 or 3, and which had actually been settled or which had expired. Credit was given for non-x-ray review passes (co-defendant settlements primarily), and MALC was excluded.

While that estimate generated an average reduction in value after x-ray review of approximately $600 per claim, and a total of a $50 million reduction in value when applied to all the currently unsettled non-malignant claims on file, it should be kept in mind that the purpose of x-ray review is not to save money, or to reduce the value of a claim. The purpose of the program is to provide an efficient and cost-effective mechanism to determine the appropriate value of ***bona fide*** claims.

The SCB has opined that claimants receiving a downgrade in category would refuse to accept that result. We examined the results of claims receiving medical audit downgrade notices (both random selections and because of B-list status) in 1996. Of the over 800 claims downgraded to Category 0 as a result of medical audit in 1996 (almost two years ago), almost 500 (59%) have expired, and only 20 have requested ADR. Similarly, approximately 1,160 claims were downgraded in medical audit to Category 1 in 1996. Of those claims, 860 (74%) have accepted the Category 1 offer, approximately 50 have requested ADR, and 60 claims have expired for lack of response.

That historical experience would indicate that a high percentage of claims that receive downgrades in medical audit will not choose to pursue the claim further. However, the SCB would argue otherwise.

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1st Quarter Claims, by Most Frequently Used Doctor

	CXR % Pass Rate	Doctor Audit @ 65%	Doctor Audit @ 60%
Harron	43%	5243	5243
Gaziano	56%	600	600
Kubler	29%	480	480
Mitchell	22%	480	480
Holmes	60%	705	
Segarra	42%	483	483
Scutero	27%	106	106
Basili	60%	114	
Schiefer	42%	102	102
Lucas	33%	97	97
Total		8410	7591
Unknown and Other Doctors w/Pass Rates <65% or <60%		755	624
ESTIMATED TOTAL CLAIMS AUDITED		9165	8215
1ST Q 1998 CLAIMS		9676	9676
MOST USED DRS AS % OF TOTAL IN QUARTER		87%	79%
AUDITED CLAIMS AS % OF TOTAL		95%	85%

NOTE: If there is no doctor record or if the Trust read fewer than 10 CXRs for a doctor, the doctor was labeled unknown.

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July 15, 2003

The Honorable Orrin G. Hatch
Chairman, Committee on the Judiciary
United States Senate
224 Senate Dirksen Building
Washington, D.C. 20510

Dear Senator Hatch:

For some years, we have been following legal and clinical problems involved in workmen's compensation programs and litigation on behalf of persons claimed to have been exposed to asbestos. One of us, (OL), was for 25 years principal staff to the American College of Radiology Task Force on Pneumoconiosis and a consultant to the National Institute for Occupational Safety and Health, and for most of those years, a member of the International Labor Office (ILO) task force on its chest x-ray classification system. The other, (JG), is a medical imaging consultant, a faculty member of the department of radiology of the Johns Hopkins Medical Institutions and a participant in the design of many studies of x-ray readings.

This letter summarizes a paper prepared by us for submission to a scientific journal on the subject of inconsistencies in the interpretation of chest radiographs required as support for claims of health damages to workers exposed to asbestos products. The abstract is attached along with one table prepared for the article. Ordinarily, we would prefer to share the published article. However, the time required for submission, peer review and eventual publication may be too late to be of assistance to you in your current proposed legislation.

A few comments about the provenance of our effort may be helpful. Since 1996, we have been providing a service to several groups of attorneys involved in asbestos litigation. They approached us seeking a way to go beyond the frequently contrary interpretations proffered by plaintiffs' experts and defense experts, most all of them B readers.

We organized a panel of expert B readers – radiologists and pulmonologists – who agreed to interpret sets of radiographs for us with no knowledge of the patients' identity, the origin of the films or even the purpose of the study. Some of our panelists have read films for attorneys on both sides, some for only defense and some not at all except for participating in our studies. The films were masked as to patient and source information before being sent to the readers, along with ILO classification forms prepared by the National Institute of Occupational Safety and Health. The full paper describes our efforts to assure the integrity and validity of our study.

The films in the study came originally from plaintiffs' counsel who chose the x-ray facility and the Initial readers noted in the attached table. Under legal rules, the 558 films were made available to defense counsel and by defense counsel to us for our proposed study. Our intent was to determine whether or not an objective group of expert readers would concur in the findings of readers selected by plaintiffs' counsel. The table reflects a wide disparity individually and collectively between the conclusions of the Initial readers and the Consultant readers. Only one Initial reader read each film while all six of the Consultant readers interpreted each film.

In addition to making the comparisons, we surveyed the world literature on x-ray studies of asbestos-related changes and could find no studies anywhere that reflected the 91.7 percent positivity (1/0 or higher for small opacities on the ILO 1980 classification) reported collectively by the Initial readers who read the same set of films prior to the Consultants reading them. The cumulative readings of our six experts was 4.5 percent positive.

The reliance of current law and regulations on chest radiographs is based upon the recognition that an x-ray film is a discrete piece of visual evidence which can be examined by many interpreters. The ILO classification system is intended to standardize interpretation and to provide a concise nomenclature for reporting findings. The dilemma is that presumably qualified interpreters may vary in their conclusions. We believe that our study demonstrates that the variation found between Initial readers and Consultant readers is statistically significant and beyond reasonable inter-reader variability.

If the individuals whose chest radiographs became part of our sample had presented themselves to medical facilities for diagnosis of their claimed respiratory difficulties, a chest radiograph would be only one element in a proper diagnostic workup. Detailed medical histories, careful physical examinations and the performance of pulmonary function tests also would be appropriate. We do not argue the perfection of chest x-ray interpretations, even in the hands of unbiased experts. We applaud your effort to improve the adjudication process.

Radiographs are representations of normal and abnormal densities in the body. It is not possible to identify from the radiograph the nature or composition of the inhaled and retained dust which causes an abnormal density. Given the smoking histories of many claimants, tobacco use must be regarded as a strong co-confounding element. The significant exception to the general statement is that pleural plaques, seen on some radiographs are pathognomic to asbestos exposure.

We offer one suggestion on your proposed language. At the beginning of the current year, the International Labor Office promulgated a new version of its classification system, dubbed ILO 2000, and described in ILO publication 22, "Guidelines for the use of the ILO international classification of radiographs of pneumoconiosis," revised edition 2000. That publication and the standard sets of reference radiographs are now available from the ILO and, if we may suggest, should be referenced in your language.

We have limited our comments to our own studies and insights. However, it is our general sense that things are broke and need fixing. We commend you and your colleagues on undertaking to fix them.

Sincerely,

Otha W Linton　　　Joseph N. Gitlin DPH

Otha W. Linton, MSJ　　　Joseph N. Gitlin, D.P.H.

Enclosures

attachment

Comparison of "B Readers" Interpretations of Chest Radiographs For Asbestos Related Changes

ABSTRACT

OBJECTIVE. The purpose of this study was to determine if chest radiographic interpretations by physicians retained by attorneys of persons alleging changes consequent to occupational asbestos exposure would be confirmed in a reading trial by independent consultant readers.

METHODS. 712 chest radiographs interpreted by B readers retained by plaintiffs' attorneys and 558 initial readings were made available to the authors. Six consultants in chest radiology, also B readers, agreed to re-read these radiographs independently without knowledge of their provenance. The film source, patient names and other identifiers were masked. The International Labor Office 1980 Classification of Chest Radiographs (ILO 80) was used with forms provided by the US National Institute of Occupational Safety and Health to record the consultants' findings. The results were compared with initial readings for film quality, parenchymal abnormalities, small opacities profusion, pleural abnormalities and incidental findings.

RESULTS. Among the many comparisons, the initial readers interpreted the study radiographs as positive for parenchymal abnormalities with a small

profusion category of 1/0 or higher in 91.7% of their 551 reports. The consultants interpreted the same set of cases as category 1/0 or higher in only 4.5% of their 3306 reports. Statistical tests of these and other comparable data from the study showed highly significant differences between the interpretations of the 30 initial readers and the findings of the consultants.

CONCLUSION. The magnitude of the differences between the interpretations by initial readers and the reports of the consultants is too great to be attributed to inter-observer differences. There is no support in the world literature for the relatively high level of positive findings recorded by the initial readers.

Small Opacities - Initial

Reader	0/-	%	0/0	%	0/1	%	1/0	%	1/1	%	1/2	%	2/1	%	2/2	%	2/3	%	3/2	%	3/3	%	3/+	%	N/S	%	Total
I-1					1	1.0	63	61.2	35	34	2	1.9									1	1.0			1	1.0	103
I-2					1	2.0	29	56.9	11	21.6			4	7.8											6	11.8	51
I-3							34	66.7	17	33.3																	51
I-4							68	94.4	3	4.2	1	1.4															72
I-5							36	94.7	1	2.6															1	2.6	38
I-6							39	70.9	15	27.3															1	1.8	55
I-7							17	45.9	14	37.8	3	8.1	1	2.7	1	2.7									1	2.7	37
Other					3	3.0	43	43.0	26	26.0	6	6.0	2	2.0	2	2.0	1	1.0					1	1.0	16	16.0	100
N/S					1	2.0	19	37.3	11	21.6	2	3.9													18	35.3	51
Total					6	1.1	348	62.4	133	23.8	14	2.5	7	1.3	3	0.5	1	0.2			1	0.2	1	0.2	44	7.9	558

Small Opacities - Consultant

Reader	0/-	%	0/0	%	0/1	%	1/0	%	1/1	%	1/2	%	2/1	%	2/2	%	2/3	%	3/2	%	3/3	%	3/+	%	N/S	%	Total
C-1					22	3.1	9	1.3	4	0.6							1	0.1							676	94.9	712
C-2					23	3.2	15	2.1	2	0.3	2	0.3	3	0.4							1	0.1			666	93.5	712
C-3			1	0.2	10	2.0	2	0.4	2	0.4	1	0.2	1	0.2	2	0.4					1	0.2			488	96.1	508
C-4					6	0.8	2	0.3	8	1.1	4	0.6					2	0.3	1	0.1	1	0.1			688	96.6	712
C-5							28	3.9	38	5.3	7	1.0	1	0.1	2	0.3	2	0.3	2	0.3	1	0.1			630	88.6	711
C-6							5	2.5	14	6.9	1	0.5			1	0.5									183	89.7	204
C-7					16	2.2	6	0.8	1	0.1	2	0.3	1	0.1	2	0.3					1	0.1			683	95.9	712
Total			1	0.0	77	1.8	67	1.6	69	1.6	17	0.4	6	0.1	7	0.2	5	0.1	3	0.1	5	0.1			4014	94.0	4271

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Letters to the Editor

Readers are invited to submit letters for publication in this department. Submit them to: The Editor, Journal of Occupational Medicine, PO Box 370, Bryn Mawr, PA 19010. Letters should be typewritten and double spaced and should be designated "For Publication."

On the Diagnostic Accuracy of Asbestos-Induced Disease

To the Editor: Despite valid attempts by the American Thoracic Society (ATS) and the American College of Chest Physicians (ACCP) to bring a degree of uniformity into the interpretation of chest radiographs for pneumoconiosis and in the performance and interpretation of lung function tests, there remains a problem when the above are applied to the diagnosis of the pneumoconioses.

We were recently asked to reinterpret the lung function tests and radiographs of 53 former asbestos workers who were longtime employees of a company that manufactured insulation products of which chrysotile was a constituent. The subjects had been asked to complete a questionnaire, had had a cursory physical examination, had undergone screening spirometry, and had had postero-anterior and lateral chest radiographs taken. As a consequence, all 53 had been told that they had asbestos-induced pleural thickening or asbestosis. The screening radiographs were initially read by the screening physician and then referred either to a B reader (J.F.) or to a very experienced reader (J.M.) who was also said to be a B reader. The screening physician's radiograph interpretations were missing in 19 subjects. In another group of 19 subjects, there had been a difference of opinion as to the diagnosis of asbestosis or extent of pleural thickening at the time of the initial reading. These subjects underwent CAT scanning.

The spirometry was subsequently repeated in a hospital-based pulmonary function laboratory and the chest radiographs were interpreted independently by three B readers, namely, P.S., N.S., and W.K.C.M. Those spirometric measurements carried out elsewhere were inspected to see whether they fulfilled the ATS criteria for reproducibility, etc.[1,2] The largest FEV_1 and FVC were accepted as the subject's value. A single breath diffusing capacity (DL_{CO}) was also measured. Morris' predicted values were used for the spirometric indices, while those of Cadigan et al were used for the diffusing capacity.[3-5]

The pulmonary function tests carried out at the screening facility and the hospital are shown in Table 1. There is an obvious disparity in the values obtained at the screening facility as compared to those obtained in the hospital. These disparities can be attributed in the main to a submaximal effort during the performance of the screening spirometry and to unsustained forced expiratory volume maneuvres. In the screening examination, around one third of the spirometric indices of the subjects did not meet the ATS criteria of acceptability, while, in contrast of the subjects tested at the pulmonary function hospital laboratory, only two did not meet the criteria, ie, the two largest values for the FEV_1 and FVC falling within 100 mL or 5% of each other. Even then, the two larger values of these two subjects were within 200 mL of each other. There was marked disagreement as to the classification of obstructive and restrictive impairment, with obstruction being underestimated because of the unsustained FVC maneuvres. All those who were obstructed were cigarette smokers. Twenty-one subjects were classified as having restrictive impairment based on the screening examination, while only seven subjects were listed as having restriction based on the measurements made at the hospital. The measurement of lung volumes showed that in only three of these seven subjects was there true restriction, with all lung volumes being decreased to roughly the same extent.

Turning to the radiological examinations, there was agreement between W.K.C.M. and N.S. and W.K.C.M. and P.W. in 84% and 83% of the radiographs and between N.S. and P.W. in 86% of the radiographs. In no instance was there disagreement of more than one subcategory and no reader interpreted any of the radiographs as showing definite asbestosis, ie, 1/0 or greater. In regard to pleural thickening, again agreement was high, but not as good as with small opacities. W.K.C.M. and N.S. and W.K.C.M. and P.W. agreed in 82% and 75% of subjects, respectively, while N.S. and P.W. agreed in 72% of subjects. Many of the subjects were obese and the differentiation between pleural thickening and pleural fat was extremely difficult in the absence of a CAT scan. In 19 subjects in whom CAT scans were available, none was read as having interstitial fibrosis; however, 14 subjects had pleural thickening or calcification. Most subjects that were reported by either J.F. or J.M. to have pleural thickening on the standard radiograph were subsequently shown to be free of pleural thickening on CAT scanning. When the radiographic interpretations of J.F. and J.M. were compared to those of W.K.C.M., N.S., and P.W., a number of disparities became obvious (Table 2). Thus, J.F. read nine out of the 14 films he interpreted as showing asbestosis, ranging 1/0 to 2/2, while J.M. read five of the 10 he read as being positive, ranging 1/0 to 1/1. Of the radiographs interpreted by the screening physician, 21 out of 34 were said to show asbestosis.

The lack of uniform criteria for the diagnosis of the mineral pneumoconioses stimulated the International Labour Office (ILO) to introduce a standard radiographic classification that could be used

TABLE 1
Lung Function Data (Percentage of Morris' Predicted)[1,2]

	Screening (% predicted)	SD	Hospital (% predicted)	SD
FVC %	83.7	11.47	91.9	12.79
FEV_1	84.9	15.49	95.35	17.49
FEV_1/FVC %	72.85	9.81	73.71	9.04
DL_{CO}*			94.5	22.36

* Gaensler's predicted values.[5]

TABLE 2
Asbestosis: Comparison of Readers' Interpretations

Subject No.	W.K.C.M.	N.S.	P.W.	J.F.	J.M.
2	0/1	0/0	0/0	2/2	
14	0/0	0/0	0/0	0/0	0/1
17	0/0	0/0	0/0	1/0	
21	0/0	0/0	0/0	1/1	
23	0/0	0/0	0/0	1/2	1/1
26	0/0	0/0	0/0	0/1	0/0
27	0/1	0/0	0/0		1/1
28	0/0	0/0	0/1	1/0	1/0
30	0/0	0/0	0/0	1/0	1/0
32	0/0	0/0	0/0	1/1	0/1
40	0/0	0/0	0/0	1/0	0/1
42	0/0	0/0	0/1	0/1	
49	0/0	0/0	0/0	0/0	0/0
52	0/0	0/0	0/0	0/0	
53	0/0	0/0	0/0	1/0	1/1

to categorize unknown radiographs.[6] Similarly, both the ATS and the European Thoracic Society have recommended standardized methods of performing and measuring the spirometric indices commonly used to measure lung function.[1–3,7] It is apparent that despite the efforts to ensure uniformity and standardization, there is still a major problem in obtaining reliable data for diagnosis and for epidemiological purposes. There is little doubt that if the recommendations of the ATS and the ILO are accepted and practiced, it is possible to reduce the variability of interpretation in both lung function tests and chest radiographs to an acceptable level.

The overinterpretation of lung function tests and of chest radiographs can cause undue and needless worry. Many of the subjects we examined were told that they had an increased risk of developing gastrointestinal cancer or mesothelioma, statements that are, for the most part, either completely unjustified or almost so.[8,9] Many workers had gained the impression that circumscribed pleural plaques invariably led to disabling impairment and subsequently developed symptoms of shortness of breath and chest pain. Many had been told to seek redress either through workers' compensation claims or through litigation, and here again one might question the advice given them. Of the 53, only one subject had definite evidence of significant asbestos-induced respiratory impairment which was due to diffuse thickening and, even then, the impairment was not disabling, at least for his job.

With such inaccurate readings being prevalent, it is difficult not to wonder about the validity of the projections made by the EPA, OSHA, and certain other government facilities as to the development of asbestos-related disease.

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Prostate Cancer and Work Environment

To the Editor: In their article entitled "Prostate Cancer and Work Environment" (*J Occup Med.* 1992;34:402–409), van der Gulden et al report the recruitment of patients with prostatic hyperplasia to serve as controls in their case-control study of risk factors for prostate cancer. The authors site both methodological and practical reasons for their decision. While choosing cases and controls from the same service (urology) is certainly *easier* than an alternative strategy, this should not influence the selection rationale if hyperplasia is, in any way, related to one or more of the etiologic factors for malignancy of the prostate. The authors indicate that "as far as is known . . ." the etiologies of these conditions are unrelated and they dismiss the finding of prostate cancer among some men with a hyperplastic prostate since "both disease are common in elderly men." This is speculative, however, and does not preclude the possibility of a relationship, as at least one study has suggested.[1]

For a disease such as prostate cancer, about which so little is known regarding its causal pathway(s), it would seem prudent to avoid the possibility of a selection bias—that is, that some proportion of the control group has a risk profile similar to the cases because one or more prostate cancer risk factors can also cause enlargement of the organ. To guard against this, the authors should have included a different (or additional) control series. Preferably, controls would have represented prostate disease-free individuals in the population who, had they developed prostate cancer, would have been identified as cases in this study.

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The Author Replies: It is a challenge to choose an appropriate reference group for a disease such as prostate cancer, with a high proportion of latent tumors. This high proportion of undetected cases is a potential source of bias. If there is, for example, a greater detection of prostate cancer among men in urban areas (living in the neighbourhood of a hospital) than among country men, the odds ratios (ORs) calculated for farmers and other rural or urban-

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VOLUME 1

TEXTBOOK OF RESPIRATORY MEDICINE

Second Edition

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Evaluation of Respiratory Impairment/Disability

John R. Balmes, M.D. • Scott Barnhart, M.D., M.P.H.

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THE ROLE OF THE PHYSICIAN IN THE EVALUATION OF IMPAIRMENT AND DISABILITY

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SUMMARY

INTRODUCTION

Respiratory impairment, which is most frequently manifested as dyspnea on exertion, can have profound effects on the ability of a patient to engage in the activities of daily living, including the ability to be gainfully employed. Evaluation of respiratory impairment generally is a multi-step process. From a strictly medical perspective, the linkage of the magnitude of symptoms, especially dyspnea, with degrees of abnormality on pulmonary function tests may be useful in the assessment of the extent or progression of a disease process. A second step, which is more difficult for physicians, involves the assessment of the impact of a patient's level of impairment on the ability to participate in activities of daily living. The most important component of this step of the evaluation is to characterize the patient's ability to become or remain gainfully employed.

Documentation of the level of respiratory impairment is also important because the patient may be entitled to a specific level of compensation for a given level of impairment.[1–4] It is often for this reason that physicians are asked to perform evaluation of respiratory impairment. Evaluation of respiratory impairment/disability for the purpose of determining eligibility for benefits is not done in a vacuum, but rather represents the intersection of the medical assessment of dysfunction with the specific requirements of compensation or entitlement programs. These programs require reproducible and valid measures of respiratory impairment from which levels of benefits can be determined.[5,6] For this reason, professional organizations of physicians such as the American Thoracic Society (ATS) and the American Medical Association (AMA) have developed guidelines for the conduct of respiratory impairment/disability evaluations.[7–9] The proper care of a patient who presents for evaluation of respiratory impairment and disability must center around answering the specific questions defined by the requirements of the entitlement or compensation system to which the patient is applying. In addition to making a clear determination of the level of respiratory impairment, the evaluating physician often has to answer questions such as whether (or how much of) the impairment can be attributed to work and whether coexisting/preexisting factors have contributed to the respiratory impairment. Although such judgments may be difficult for physicians to make, they are necessary if both the patient and compensation program are to be well served. It is important to remember that regardless of the evaluating physician's opinions, the final decision to award compensation usually resides with an administrative body.[2,3,10,11] Age, level of education, previous training/experience, and job availability in the geographic area are some of the non-medical factors that are considered by agencies responsible for disability determination.

THE ROLE OF THE PHYSICIAN IN THE EVALUATION OF IMPAIRMENT AND DISABILITY

Not every physician who performs evaluations for impairment and disability is the patient's treating or personal physician. A clear understanding by both the patient and evaluating physician of the responsibilities and limitations of the role of evaluating physician in the disability rating process is an important element in the provision of good service to the patient and the system from which the person is seeking benefits. Physicians performing evaluations for impairment/disability generally fit two categories: treating physicians (personal physicians) and independent medical examiners. Treating physicians maintain the usual patient-physician relationship, but they are still required to present their findings in an objective and unbiased manner. As a result of the extensive knowledge of treating physicians about the health of their patients, their opinions usually carry substantial weight in an impairment/disability evaluation. On the other hand, treating physicians may find it difficult to remain unbiased and may feel that a fully objective assessment could jeopardize their relationship with a patient, or they may not have particular expertise in the assessment of respiratory impairment. Because treating physicians may be perceived as being biased or lacking expertise, patients are often referred to other physicians who act as independent medical examiners. Independent medical examiners, who should be expected to have expertise in the evaluation of impairment/disability, are paid by the referring administrative agency. The role of the independent medical examiner is to provide an objective and unbiased evaluation. The usual physician-patient relationship is not established, and the physician does not become involved in treatment beyond making recommendations to the treating physician. Regardless of which role is being played, it is incumbent upon the evaluating physician to inform the patient of the nature of that role and potential sources of bias such as source of referral.[4, 12] Because of the obvious potential for bias on the part of either the treating physician or the independent medical examiner, neither should necessarily be accorded the final opinion in a given case.

Evaluating physicians should strive to get patients to recognize that the evaluation of impairment/disability is a multi-step process in which physicians assess impairment and the award of benefits is decided at an administrative level. While the physician's input is important, patients must understand that the physician does not have control over the acceptance of claims or level of benefits awarded. Patient recognition of the role of the evaluating physician and the limitations of that role in the disability rating process is crucial to the avoidance of serious misunderstandings (which may even jeopardize long-standing physician-patient relationships).[4]

DEFINITIONS

Because the evaluation of impairment/disability represents a marriage of medical practice with legal and administrative rules, an understanding of the definitions of key terms is essential. The following terms are frequently used in the evaluation process:

Dyspnea is "the sensation of undue and/or uncomfortable awareness of breathing."[10]

Impairment is "the reduction of body or organ function."[10]

Disability is "the inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment or impairments."[10]

Handicap is "the disadvantage for a given individual, resulting from impairment or disability, that limits or prevents fulfillment of a role that is normal (depending upon age, sex, and social and cultural factors) for that individual" (World Health Organization definition).[13]

Subjective refers to symptoms "perceived by the patient only and not evident to the examiner."[14]

Objective refers to findings evident to the examiner in a reproducible manner and not dependent only on the patient's perceptions.

Preexisting refers to any impairment or disease that existed prior to the onset of another disease or impairment (see coexisting).

Coexisting refers to any impairment or disease that exists concurrently with another disease or impairment (see preexisting).

Organic impairment is an "impairment explained on the basis of demonstrable abnormality, dysfunction, or disease."[10]

Functional impairment is an "impairment not explained on the basis of demonstrable abnormality, dysfunction, or disease."[10]

Permanent partial disability is a disability at a level less than total disability that is not expected to improve.

Permanent total disability is a disability that prevents gainful employment and that is not expected to improve.

Temporary disability is either total or partial disability that is thought to have a high probability of being short-term and thus can be expected to improve to a higher level of function.

DYSPNEA

The sensation of dyspnea on exertion is, by far, the most common reason for individuals to seek evaluation for respiratory impairment/disability. From the patient's perspective, dyspnea is the "gold standard" against which the disability should be rated. From the perspective of most entitlement systems, such as workers' compensation systems, it is the ability of an individual to do a job that is the gold standard against which dyspnea and physiologic impairment must be assessed. Both dyspnea and measures of physiologic impairment (static and exercise pulmonary function tests) will be discussed shortly with respect to their predictive validity.

Dyspnea is defined as a sensation of undue or uncomfortable awareness of breathing, or both. Although dyspnea is the reason behind the patient's perception of a respiratory impairment/disability, it is usually not a component of the final rating schemes for determining awards for impairment and disability. For obvious reasons, compensation programs require objective measures of respiratory impairment. Nonetheless, the absence of objective findings consistent with the level of dyspnea should not necessarily indicate that the patient's complaint is not valid.[15–17]

A comprehensive review of the pathophysiology of dyspnea is beyond the scope of this chapter, but the subject is explored in detail in Chapter 19. Briefly, the physiologic causes of dyspnea include the response of central chemoreceptors to changes in arterial P_{CO_2} and to a lesser extent changes in arterial P_{O_2}, as well as the stimulation of peripheral mechanoreceptors in respiratory muscles.[18–19] Within the lungs, dyspnea may be caused by stimulation of irritant receptors by physical or chemical exposures, stretch receptors by changes in lung volume, and C-fiber receptors by changes in vascular pressures. In the setting of increased minute ventilation, increased airway resistance, increased lung recoil, or respiratory muscle weakness, the sensation of dyspnea will increase. The sensation will, however, be modified by other physiologic or psychologic factors to manifest as a symptom along a continuum that ranges from a mild awareness of being short of breath to an extremely unpleasant feeling. Disease processes that involve the chest wall, respiratory muscles, lung parenchyma, upper or lower airways, and pulmonary arteries or veins are all capable of causing dyspnea.[20, 21]

With respect to impairment/disability, the mild awareness of dyspnea may be correlated with mild physiologic impairment, but is unlikely to represent disability. The more uncomfortable and unpleasant manifestations of dyspnea may also be correlated with more severe objective measures of respiratory impairment and may be sufficiently severe to limit a patient's ability to perform certain tasks on the job. Although ratings of dyspnea correlate with multiple objective measures of impairment, the degree of correlation is not high.[16, 16a, 22] The factors contributing to this relative lack of correlation include the following: limitations in the sensitivity and specificity of dyspnea scales; multifactorial causes of dyspnea (e.g., coexisting physiologic contributors to impairment, such as pulmonary and cardiac dysfunction, or psychologic factors such as anxiety); and rarely, the occurrence of frank malingering. Each of these factors is briefly discussed below.

Dyspnea Scales

Multiple attempts have been made to characterize dyspnea in a reproducible and externally valid manner.[9, 20, 22–26, 26a] Grading dyspnea can provide reasonable benchmarks to relate degree of symptoms to level of activity. Dyspnea grades can also be used to assess whether abnormalities of pulmonary function tests correlate with the extent of dyspnea.[16, 22] The failure of symptoms to match the expected results on pulmonary function tests should prompt the examining physician to search for additional causes of dyspnea.

Physiologic Correlates and Validation of Dyspnea

Dyspnea can be correlated with a number of pulmonary function tests. There are four major categories of pulmonary function testing that have traditionally been used to assess dyspnea and are used in the evaluation of impairment. These are simple spirometry: FVC, FEV_1, the FEV_1/FVC ratio, maximal voluntary ventilation (MVV), single breath diffusing capacity (DL_{CO}), and exercise testing. The results of none of these tests are perfectly correlated with dyspnea.[16] In addition, static pulmonary function tests such as spirometry or DL_{CO} are not well correlated with measures of work such as maximal oxygen consumption ($\dot{V}O_{2\,max}$).[27] In patients with chronic obstructive pulmonary disease, the correlation between dyspnea rated at the end of a standardized walking protocol and measures of pulmonary function was strongest with MVV (correlation coefficient -0.78), FEV_1 (correlation coefficient -0.71), and FVC (correlation coefficient -0.68).[16] There is some evidence that among subjects with chronic airflow obstruction, those with severe dyspnea have lower DL_{CO} values than those with milder dyspnea.[27a] Among patients with diffuse interstitial lung diseases such as sarcoidosis, chronic interstitial pneumonitis, and pneumoconioses, the strongest correlation between severity of dyspnea after a standardized walking protocol was with DL_{CO} (correlation coefficient -0.50), with the correlation coefficients for FVC, FEV_1,

FEV_1/FVC, and MVV being −0.41, −0.40, −0.08, and −0.38, respectively.[16]

When a baseline questionnaire rating of dyspnea was compared with the dyspnea rated at the end of the standardized walking protocol, the correlation coefficient (0.56) was less than that seen with MVV, FEV_1, or FVC.[16] This suggests that when the standard is dyspnea occurring as a result of physical exertion, subjective estimates of dyspnea, based on recall when the patient is at rest, may be less predictive than spirometry.

Exercise testing has been strongly advocated as the gold standard for assessing a patient's capacity to perform work.[28] Although exercise testing does give a measure of a patient's aerobic power, there are relatively few data to support the predictive value of exercise testing for assessing a patient's ability to perform a specific job. This is probably related to the difficulties of estimating energy requirements for specific jobs, especially those that may require multiple periods of variably intense physical work, than it is related to shortcomings in exercise testing. When exercise testing is used to predict work capacity, the average energy requirements over an 8-hour work day should not exceed between 30% to 40% of $\dot{V}O_{2max}$.[29–32] However, this guideline does not preclude short periods of more intense work exceeding 40% $\dot{V}O_{2max}$.

With respect to exercise testing, a patient's estimate of dyspnea in relation to a level of physical activity is a relatively poor predictor of maximal exercise capacity.[21, 22] When the results of resting pulmonary function tests are used to predict $\dot{V}O_{2max}$, the predictive power of either spirometry and DL_{CO} is relatively poor.

Although exercise testing may be the best indicator of an individual's ability to perform work, it is not the sole indicator of impairment. If the question posed to the physician is whether a patient can perform a given job, symptoms are of limited value. Static pulmonary function tests are of greater value, but less so than exercise testing. The convenience and low cost of static pulmonary function tests must be weighed against the benefits of exercise testing for rating specific job disability. If, however, the question posed to the physician is whether a loss of function has occurred so that appropriate compensation following an injury or illness can be determined, then static pulmonary function tests, which have well-described normative values, provide a better estimate of the degree of impairment.

Malingering

No discussion on evaluation of respiratory impairment is complete without addressing malingering.[33] As noted above, respiratory impairment can be categorized as organic or functional.[17] Organic impairment refers to the presence of objective findings of respiratory dysfunction or disease. Organic dyspnea may also be caused by non-respiratory disorders such as cardiac disease and anemia. Functional impairment refers to dyspnea for which an objectively measured abnormality of organ function cannot be identified. Recognizing that tests for organic impairment are not perfectly sensitive, the contribution of functional impairment can range from negligible to perhaps accounting for the entire extent of a patient's dyspnea. Dyspnea due to functional impairment may result from subconscious effects on perception or outright malingering. Malingering has been characterized as encompassing "all forms of fraud relating to matters of health. This includes the simulation of diseases or disability which is not present; a much commoner gross exaggeration of minor disabilities; and a conscious and deliberate attribution of a disability to an injury or accident that did not in fact cause it, for personal advantage."[34]

There is little question that malingering occurs, although it is thought to be relatively uncommon. Because of the inability of pulmonary function tests and other tests to be perfectly sensitive in diagnosing organic causes of impairment, the diagnosis of malingering should be a diagnosis of exclusion. Nonetheless, one study documented that patients applying for compensation often have a higher grade of breathlessness for a given level of FEV_1 than patients being referred for other reasons.[35] This study also reported a positive association between dyspnea and body weight, highlighting the potential multifactorial nature of breathlessness. To state that these overweight patients with dyspnea were outright malingerers would probably be unfair. To ignore the potential for dyspnea to be overestimated, however, would be naive. It is for these reasons that most entitlement programs and compensation systems rely only upon objective data for impairment ratings and often require specific tests and performance criteria to ensure the validity of the results.

When malingering is a concern, there are several steps that may assist in the evaluation. The first and foremost is to review the purpose of the evaluation with the patient to ensure that a lack of comprehension of either questions or performance of pulmonary function tests is not misconstrued as frank malingering. Second, an evaluation of test performance, including cooperation and the results of effort-independent tests such as functional residual capacity, may be of some use. Unfortunately, spirometry is to some extent effort-dependent, although the use of ATS performance criteria clearly improves reliability. Examination of test results for comparability over time may show evidence of consistency or lack thereof. Finally, exercise testing may shed considerable light on a patient's level of effort by demonstrating the relationships of heart rate and ventilatory rate at workloads actually

Table 30–1. American Medical Association Classification of Respiratory Impairment*

Class 1 0%: No Impairment of the Whole Person	Class 2 10%–15%: Mild Impairment of the Whole Person	Class 3 30%–45%: Moderate Impairment of the Whole Person	Class 4 50%–100%: Severe Impairment of the Whole Person
FVC ≥ 80% of predicted, and FEV_1 ≥ 80% of predicted, and FEV_1/FVC ≥ 70%, and DL_{CO} ≥ 80% of predicted.	FVC between 60% and 79% of predicted, or FEV_1 between 60% and 79% of predicted, or FEV_1/FVC between 60% and 69%, or DL_{CO} between 60% and 79% of predicted.	FVC between 51% and 59% of predicted, or FEV_1 between 41% and 59% of predicted, or FEV_1/FVC between 41% and 59%, or DL_{CO} between 41% and 59% of predicted.	FVC ≤ 50% of predicted, or FEV_1 ≤ 40% of predicted, or FEV_1/FVC ≤ 40%, or DL_{CO} ≤ 40% of predicted.
or	or	or	or
$\dot{V}O_{2max}$ > 25 mL/kg/min	$\dot{V}O_{2max}$ between 20 and 25 mL/kg/min	$\dot{V}O_{2max}$ between 15 and 20 mL/kg/min	$\dot{V}O_{2max}$ < 15 mL/kg/min

*Modified with permission from the American Medical Association: Guides to the Evaluation of Permanent Impairment, 3rd rev. ed. Chicago, American Medical Association, 1991.

achieved to predicted maximal values. Although it is important to identify frank malingering, which represents fraud, we must again emphasize that malingering is relatively rare, and should remain a diagnosis that is made by exclusion and with caution. All pulmonary function tests are discussed in Chapter 28.

CLASSIFICATION SYSTEMS FOR IMPAIRMENT AND DISABILITY

Respiratory impairment can be classified using professional organization-approved guidelines such as those of the AMA, ATS, Canadian Medical Association, or European Society for Clinical Respiratory Physiology.[7–9, 36, 37] The entitlement program for which a given patient is being evaluated may not recognize any of these guidelines, however, and may require instead use of a program-specific classification scheme..

Entitlement programs include Social Security Disability Insurance, state-based welfare eligibility programs, and workers' compensation insurance. Workers' compensation encompasses a broad array of programs covering employees of privately owned firms (usually covered by state-based systems), employees of federal agencies, shipyard and railway workers, and veterans of the armed services. Central to workers' compensation is the premise that eligibility is based on the attribution of a patient's impairment to work. Similarly, under tort law or what is often termed third-party liability litigation, impairment that is attributable to some form of injury is frequently rated for the purposes of determining the level of compensation. Many people are eligible for benefits through employer-related disability programs or other insurance-based disability programs. There are also non-monetary programs that provide benefits such as disabled parking stickers or bus passes and require a physician's determination of a certain level of disability. With the advent of the Americans with Disabilities Act, these latter categories are likely to be expanded.

Each of the above entitlement systems may choose different important criteria for eligibility for disability benefits. In the absence of a requirement for the use of another classification scheme, the use of the *Guides to the Evaluation of Permanent Impairment* published by the AMA is the best approach to impairment rating.[9] In this section, the widely used AMA *Guides* will be reviewed along with some specific ATS recommendations for use of exercise testing and the evaluation of patients with asthma.

American Medical Association: Guides to Evaluation of Permanent Impairment

The guidelines published by the AMA provide specific recommendations and considerations with respect to the medical history, physical examination, and laboratory tests used for the evaluation of impairment.

In the AMA *Guides*, respiratory impairment is broken into four classes, as shown in Table 30–1. Each of the classes, ranging from no impairment or normal through mild and moderate impairment to severe impairment, is defined by criteria based on the results of spirometry (FVC, or FEV_1, or FEV_1/FVC), or DL_{CO}, or level of $\dot{V}O_{2max}$ on exercise testing. The AMA *Guides* recommend, at a minimum, that spirometry and DL_{CO} be obtained in the course of evaluation of impairment. Of course, if good-quality spirometry has already documented a severe impairment, the results of the DL_{CO} would not change the outcome of the evaluation.

The *Guides* include a recommendation that the subjective level of severity of dyspnea not be used as a basis for rating impairment nor should the findings on chest roentgenograms. Measuring arterial blood gases are not recommended as part of the standard evaluation, but a resting arterial PO_2

of less than 50 mm Hg is a criterion for severe impairment as is an arterial Po_2 of less than 60 mm Hg if other abnormalities such as pulmonary hypertension, cor pulmonale, increasingly severe hypoxemia during exercise, or erythrocytosis are present.

The use of exercise testing is not recommended when severe impairment is demonstrated by spirometry or DL_{CO}. Exercise testing is felt to be of benefit when subjective complaints are out of proportion to the findings on spirometry and DL_{CO}, when the patient claims to be physically unable to meet the energy demands of a specific job secondary to dyspnea, or when the patient appears to be unable to give a maximal or adequate effort on spirometry.

Under the AMA approach, a rating of a given class of impairment is obtained by comparing the patient's performance on spirometry (in terms of FVC, FEV_1, or FEV_1/FVC), DL_{CO}, or $\dot{V}O_{2max}$ with the criteria for each class. Of note, the DL_{CO} is considered primarily of value for patients with interstitial lung disease. If the results of spirometry are normal, even if the DL_{CO} meets the criteria for mild or moderate impairment, exercise testing for $\dot{V}O_{2max}$ is required. With this proviso, the *Guides* indicate that the class of impairment can be determined by the lowest single parameter of lung function among those listed. It is more appropriate, however, to seek a class that provides the best overall fit of a patient's test results with the level of impairment described for the class.

The AMA *Guides* recommend that spirometry be performed when the patient is at optimal health and after administration of an inhaled bronchodilator. Test performance should follow the ATS protocols for both spirometry and DL_{CO}.[38, 39] The rating of impairment under the AMA *Guides* using the results of spirometry and DL_{CO} is based on the percentage ratio of the patient's observed value to the predicted value with the exception of the FEV_1/FVC ratio for which the absolute value is used. The *Guides* provide tables of normal values based on regression equations for spirometric parameters and DL_{CO}.[40, 41] Adjustment for predicted normal values is recommended only for African-American and Asian patients and not for patients from other ethnic groups, who should be rated using the unadjusted reference values for Caucasians. For patients of African-American and Asian descent, the Caucasian predicted values should be multiplied by 0.9 before being used to calculate percent predicted values. No guidance is provided for patients of mixed racial descent, and the use of Caucasian predicted values is probably the best approach to these patients.

The *Guides* also briefly discuss, and make specific recommendations for, evaluation of impairment due to asthma, hypersensitivity pneumonitis, pneumoconiosis, sleep disorders, and lung cancers. Asthma is felt to represent severe impairment if, on three successive measures each spaced 1 week apart, pulmonary function remains at the class IV level. In addition, employment-related disability for patients with occupational asthma, who should not be further exposed to sensitizers such as isocyanates, is recognized. Hypersensitivity pneumonitis is also recognized as a reason for removal of the patient from further exposure to the putative antigen. Similarly, the diagnosis of pneumoconiosis, even in the absence of physiologic impairment, is considered sufficient reason for removal from further exposure to the causative dust. Sleep apnea is recognized to cause multiple organ impairment and should be rated based on the *Guides'* criteria for impairment of the nervous system and cardiovascular system and for impairment due to mental and behavioral disorders. Impairments in each of these categories are then combined, in a less than additive fashion, according to a prescribed formula. Finally, individuals with lung cancer are considered severely impaired at the time of diagnosis. Re-evaluation is recommended at 1 year following the initial diagnosis. If the patient is free of tumor at that time, then the residual respiratory impairment should be rated according to the usual criteria. Continued presence of tumor at one year or recurrence at a later date is considered to represent severe impairment.

American Thoracic Society: Evaluation of Impairment/Disability Secondary to Respiratory Disorders

With respect to spirometry and DL_{CO}, the 1986 ATS criteria[8] are nearly identical to those of the AMA *Guides*. This is not surprising, given that the AMA explicitly acknowledges that its criteria are based upon those developed by the ATS. The major difference between the two classification schemes involves the use of exercise in the evaluation of impairment. The ATS emphasizes the importance of matching measured exercise capacity with the estimated energy requirements of a job. Oxygen consumption values are described for several broad categories of activities and workers are felt to be able to perform a job comfortably if the $\dot{V}O_2$ required by a specific job is 40% or less of the patient's $\dot{V}O_{2max}$.

The ATS has recently approved a new classification scheme for rating impairment/disability due to asthma.[42] Under the new ATS scheme, impairment due to asthma will be rated through the use of five classes. The rating is determined by the sum of scores from three categories (Table 30–2): postbronchodilator FEV_1; airway hyperresponsiveness as measured by either reversibility of FEV_1 after bronchodilator inhalation or the provocative concentration of methacholine (or histamine) that causes a 20% decrease in FEV_1 from the pre-challenge baseline (PC_{20}); and medication requirements for optimal therapy. These criteria are felt to provide a far more accurate characterization of impairment in patients with variable levels of pulmonary function due to asthma than those of the AMA *Guides* or the Social Security Disability Insurance Program.

Table 30–2. American Thoracic Society Asthma Impairment Rating Scheme*

A. Post-Bronchodilator FEV_1†

Score	*FEV_1 (% predicted)*
0	> lower limit of normal
1	70–lower limit of normal
2	60–69
3	50–59
4	< 50

B. Reversibility of FEV_1 or Degree of Airway Hyperresponsiveness†

Score	*% FEV_1 Change*	*PC_{20}‡ (mg/mL)*
0	< 10	> 8
1	10–19	8–> 0.5
2	20–29	0.5–> 0.125
3	> 30	≤ 0.125

C. Minimum Medication Need§

Score	*Medication*
0	No medication
1	Occasional bronchodilator, not daily, and/or occasional cromolyn, not daily
2	Daily bronchodilator and/or daily cromolyn and/or daily low-dose inhaled steroid (< 800 μg beclomethasone or equivalent)
3	Bronchodilator on demand and daily high-dose inhaled steroid (> 800 μg beclomethasone or equivalent) or occasional course (1–3/yr) systemic steroid
4	Bronchodilator on demand and daily high-dose inhaled steroid (> 1,000 μg beclomethasone or equivalent) and daily systemic steroid

D. Summary of Impairment Rating Classes¶

Impairment Class	*Total Score*
0	0
I	1–3
II	4–6
III	7–9
IV	10–11
V	Asthma not controlled despite maximal treatment; i.e., FEV_1 remaining < 50% despite use of ≥ 20 mg prednisone/day

*Modified with permission from the American Thoracic Society: Guidelines for the Evaluation of Impairment/Disability in Patients with Asthma. Am. Rev. Respir. Dis. In press.

†When the post-bronchodilator FEV_1 value is above the lower limit of normal, the PC_{20} value should be determined and used for rating of impairment; when the post-bronchodilator FEV_1 value is < 70% of the predicted value, the degree of reversibility should be used; when the FEV_1 value is between 70% of the predicted value and the lower limit of normal, either the degree of reversibility of FEV_1 or the PC_{20} can be used.

‡PC_{20}, 20% decrease in FEV_1 from the pre-challenge baseline.

§The need for minimum medication should be demonstrated by the treating physician, e.g., previous records of exacerbation when medications have been reduced.

¶The impairment rating is calculated as the sum of the patient's scores from Tables A, B, and C.

SPECIFIC ENTITLEMENT SYSTEMS

Social Security Disability

The Social Security Administration is responsible for the Social Security Disability Insurance Program and the Supplemental Security Income Program. The former program entitles disabled workers who previously contributed to Social Security to benefits. The latter program provides a minimum income level for disabled persons who meet criteria for financial need. To be eligible, patients must have an impairment sufficiently severe to prevent them from working for a period of 1 year or longer. The Social Security Administration provides strict criteria for eligibility. Major categories for which there are specific criteria include chronic obstructive pulmonary disease (COPD) (discussed in Chapter 41), chronic restrictive ventilatory disorders (discussed in Chapter 58), and chronic impairment of gas exchange. Tables 30–3, 30–4, and 30–5 present the criteria for eligibility for each of these categories under Social Security. It should be noted that these criteria are not adjusted for sex or age, so older women are more likely to be rated as disabled than younger men for the same level of impairment.[43]

Additional disorders that are considered under the Social Security disability rating scheme include asthma (discussed in Chapter 40), pneumoconiosis (Chapter 66), bronchiectasis (Chapter 42), mycobacterial infection (Chapter 35), and pulmonary hypertension (Chapter 52). Eligibility for disability benefits for asthma can be obtained either by meeting the criteria for COPD or by documenting the occurrence of severe attacks at least every 2 months, or an average of six per year, with wheezing docu-

Table 30–3. Social Security Disability Evaluating Criteria for Chronic Obstructive Pulmonary Disease*

	FEV_1 and MVV†	
Height Without Shoes (inches)	**Equal to or Less Than (L, BTPS‡)**	**MBC Equal to or Less Than (L/min, BTPS‡)**
60 or less	1.0	40
61–63	1.1	44
64–65	1.2	48
66–67	1.3	52
68–69	1.4	56
70–71	1.5	60
72 or more	1.6	64

*Modified with permission from Social Security Administration: Disability Evaluation under Social Security. HHS Publication No. (SSA) 64-039. Baltimore, MD, Department of Health and Human Services, 1992.

†MVV, maximal voluntary ventilation.

‡BTPS, body temperature and pressure saturated with water vapor.

Table 30–4. Social Security Disability Criteria for Evaluating Chronic Restrictive Disorders*

Height Without Shoes (inches)	Vital Capacity Equal to or Less Than (L, BTPS)
60 or less	1.2
61–63	1.3
64–65	1.4
66–67	1.5
68–69	1.6
70–71	1.7
72 or more	1.8

*Modified with permission from Social Security Administration: Disability Evaluation under Social Security. HHS Publication No. (SSA) 64-039. Baltimore, MD, Department of Health and Human Services, 1992.

mented in between attacks. Pneumoconioses are evaluated by the criteria for obstructive, restrictive, or gas-exchange impairments. Patients with bronchiectasis who have airway anatomic abnormalities documented by specific imaging techniques and who have pneumonia or bronchitis every 2 months are eligible. Patients with bronchiectasis are also eligible if they meet impairment criteria for obstructive, restrictive, or gas-exchange disorders. Patients with mycobacterial infection are also evaluated by the criteria for obstructive, restrictive, or gas-exchange impairments. Finally, to be eligible, patients with pulmonary hypertension must meet specific criteria for right ventricular hypertrophy. It is important to note that many patients fail to meet the strict eligibility criteria of the Social Security Administration. Patients with multiple diseases contributing to their total impairment should have each impairment documented in their applications. Patients who appeal initial rejections are more likely to receive benefits eventually than those who do not.[26]

Workers' Compensation

Workers' compensation insurance is designed to provide benefits for medical care and wage replacement for workers who are injured or develop illnesses attributed to their work.[44] Each state has its own workers' compensation system. In addition, there are multiple separate systems for workers in various trades, including federal employees (Office of Workers Compensation), military personnel (Veterans Administration), shipyard workers, railway workers, and merchant mariners. The latter two categories of workers are covered by liability acts that require the injured worker to retain an attorney in order to file a claim.

Table 30–5. Social Security Disability Criteria for Evaluating Chronic Impairment of Gas Exchange*

1. Steady-state exercise blood gases demonstrating values of Pa_{O_2} and simultaneously determined Pa_{CO_2}, measured at a workload of approximately 17 mL O_2/kg per minute or less of exercise, equal to or less than the values specified below.

Applicable at Test Sites Less Than 3,000 Feet Above Sea Level		Applicable at Test Sites 3,000 Through 5,000 Feet Above Sea Level		Applicable at Test Sites Over 6,000 Feet Above Sea Level	
Arterial P_{CO_2} (mm Hg) and	Arterial P_{O_2} and Equal to or Less Than (mm Hg)	Arterial P_{CO_2} (mm Hg) and	Arterial P_{O_2} and Equal to or Less Than (mm Hg)	Arterial P_{CO_2} (mm Hg) and	Arterial P_{O_2} and Equal to or Less Than (mm Hg)
30 or below	65	30 or below	60	30 or below	55
31	64	31	59	31	54
32	63	32	58	32	53
33	62	33	57	33	52
34	61	34	56	34	51
35	60	35	55	35	50
36	59	36	54	36	49
37	58	37	53	37	48
38	57	38	52	38	47
39	56	39	51	39	46
40 or above	55	40 or above	0	40 or above	45

or

2. Diffusing capacity for the lungs for carbon monoxide less than 6 mL/mm Hg per minute (steady-state methods) or less than 9 mL/mm Hg per minute (single breath method) or less than 30% of predicted normal. (All methods, actual values and predicted normal values for the methods used should be reported.)

*Modified with permission from Social Security Administration: Disability Evaluation under Social Security. HHS Publication No. (SSA) 64-039. Baltimore, MD, Department of Health and Human Services, 1992.

For workers to receive compensation, their illnesses must be attributed on a "more probable than not" (i.e., likelihood of 51%) basis to a workplace exposure. Because of the multifactorial nature of many illnesses (e.g., COPD in a worker who smokes cigarettes and who also is exposed to isocyanate paints) and the long latency between some exposures and the development of disease, the process of attributing an illness to workplace exposure is difficult and frequently contested.[44]

Under workers' compensation, treating physicians may have to make a decision to remove a patient immediately from the workplace in situations where continued exposure constitutes a significant health hazard. In this situation, it is appropriate for the patient to file a claim for compensation and for the physician to place the patient on temporary total disability until the medical condition resolves and/or the hazardous exposure at work is controlled. In this and other cases, where attribution to work is made on a "more probable than not" basis, the physician is obligated to assist with filing a workers' compensation claim.

Department of Veterans Affairs

Veterans may apply for service-connected disability through the Veterans Administration. The Veterans Administration has a highly codified rating system for impairment.[45] Under the Veterans Administration specific diseases are rated on a 0 to 100% basis. The ratings are based on symptoms and pulmonary function tests. Specific levels of pulmonary function test abnormalities are not used to assign the level of impairment, however. This provides the opportunity for substantial interpretation by the evaluating physician. Table 30–6 provides the current ratings for chronic bronchitis, bronchiectasis, asthma, emphysema, and pneumoconiosis. Additional respiratory diseases such as tuberculosis and lung abscess (discussed in Chapter 34) are also covered under this system.

Black Lung Benefits Act

Miners who file claims under this program are afforded an opportunity to substantiate their claims by an evaluation consisting of a chest roentgenogram, a physical examination, and pulmonary function tests, including arterial blood gas measurements.[1, 46] Eligibility for benefits under the Black Lung Act is dependent upon the presence of chest roentgenographic evidence of pneumoconiosis when the roentgenogram is classified according to the International Labour Organisation (ILO) system. Alternatively, eligibility may be established by biopsy or autopsy evidence of pneumoconiosis, or, in the face of a negative chest roentgenogram, a reasoned medical opinion finds that the miner suffers or suffered from pneumoconiosis. An eligible miner or the dependents can receive benefits if the miner is totally disabled as a result of pneumoconiosis. Total disability is considered to be present "if pneumoconiosis prevents or prevented the miner: from performing the usual coal mine work; and from engaging in gainful employment in the immediate area of his or her residence requiring the skills or abilities comparable to those of any employment in a mine or mines in which the person previously engaged with some regularity over a substantial period of time."[46] To establish disability, the results of pulmonary function tests should be equal to or less than specified values. Knudson regression equations should be used to generate predicted values for spirometry.[47] The value representing disabling impairment for FEV_1 is equivalent to 58% of the predicted value for a 50-year-old man who is 72 inches tall using the Crapo reference values recommended by the ATS/AMA guidelines.[8, 9, 40] There are also criteria for MVV and arterial blood gas values. Again, a reasoned medical opinion can be used to establish total disability if pulmonary function testing is contraindicated.

CLINICAL APPROACH TO THE EVALUATION OF RESPIRATORY IMPAIRMENT

The evaluation of a patient for possible respiratory impairment is a multi-component process that is outlined in Table 30–7.

History

Even though the purpose of the evaluation is to determine the patient's respiratory impairment, a complete and thorough medical history, including a detailed occupational history, is essential.[8, 9] Special attention should be given to the symptoms of dyspnea, cough, sputum production, wheezing, and chest tightness. If any of these symptoms is present, its intensity, time of onset, duration, and progression should be described carefully. A standardized approach to the characterization of respiratory symptoms is recommended, and administration of a questionnaire with questions from the ATS Epidemiology Standardization Project may provide a good starting point.[25] Whether a questionnaire is used or not, an attempt should be made to rate the severity of the patient's dyspnea by means of a scale or classification scheme, such as that suggested by the AMA (see Table 30–8).

Although cough is a frequent symptom in patients with respiratory disease, only some patients will meet the traditional clinical definition of chronic

Table 30–6. Veterans Administration Rating Schedule for Chronic Obstructive Pulmonary Disease, Asthma, and Pneumoconiosis*

Disease	Rating
Chronic bronchitis	
Pronounced: with copious productive cough and dyspnea at rest; pulmonary function testing showing a severe degree of chronic airway obstruction; with symptoms of associated severe emphysema or cyanosis and findings of right-sided heart involvement	100
Severe: with severe productive cough and dyspnea on slight exertion and pulmonary function tests indicative of severe ventilatory impairment.	60
Moderately severe: persistent cough at intervals throughout the day, considerable expectoration, considerable dyspnea on exercise, rales throughout chest, beginning chronic airway obstruction	30
Moderate: considerable night or morning cough, slight dyspnea on exercise, scattered bilateral rales	10
Mild: slight cough, no dyspnea, few rales	0
Bronchiectasis	
Pronounced: symptoms in aggravated form, marked emphysema, dyspnea at rest or on slight exertion, cyanosis, marked loss of weight or other evidence of severe impairment of general health	100
Severe: with considerable emphysema, impairment in general health manifested by loss of weight, anemia, or occasional pulmonary hemorrhages; occasional exacerbations of a few days' duration, with fever, etc., are to be expected; demonstrated by lipiodol instillation and layer sputum test.	60
Moderate: persistent paroxysmal cough at intervals throughout the day, abundant purulent and fetid expectoration, slight, if any, emphysema or loss of weight.	30
Asthma†	
Pronounced: asthmatic attacks very frequently with severe dyspnea on slight exertion between attacks and with marked loss of weight or other evidence of severe impairment of health.	100
Severe: frequent attacks of asthma (one or more attacks weekly), marked dyspnea on exertion between attacks with only temporary relief by medication; more than light manual labor precluded.	60
Moderate: asthmatic attacks rather frequent (separated by only 10- to 14-day intervals) with moderate dyspnea on exertion between attacks.	30
Mild: paroxysms of asthmatic type breathing (high-pitched expiratory wheezing and dyspnea) occurring several times a year with no clinical findings between attacks.	10
Emphysema	
Pronounced: intractable and totally incapacitating; with dyspnea at rest, or marked dyspnea and cyanosis on mild exertion; severity of emphysema confirmed by chest roentgenograms and pulmonary function tests.	100
Severe: exertional dyspnea sufficient to prevent climbing one flight of steps or walking one block without stopping; ventilatory impairment of severe degree confirmed by pulmonary function tests with marked impairment of health.	60
Moderate: with moderate dyspnea occurring after climbing one flight of steps or walking more than one block on level surface; pulmonary function tests consistent with findings of moderate emphysema.	30
Mild: with evidence of ventilatory impairment on pulmonary function tests and/or definite dyspnea on prolonged exertion.	10
Pneumoconiosis	
Pronounced: with extent of lesions comparable to far advanced pulmonary tuberculosis or pulmonary function tests confirming a markedly severe degree of ventilatory deficit; with dyspnea at rest and other evidence of severe impairment of bodily vigor producing total incapacity.	100
Severe: extensive fibrosis, severe dyspnea on slight exertion with corresponding ventilatory deficit confirmed by pulmonary function tests with marked impairment of health.	60
Moderate: with considerable pulmonary fibrosis and moderate dyspnea on slight exertion, confirmed by pulmonary function tests.	30
Mild: definitely symptomatic with pulmonary fibrosis and moderate dyspnea on extended exertion.	10

*Modified with permission from Veterans Administration. Code of federal regulations: Pensions, bonuses, and veterans relief. Vol. 38. US Government Printing Office, 1991, pp. 346–398.
†In the absence of clinical findings of asthma at time of examination, a verified history of asthmatic attacks must be of record.

bronchitis: cough productive of sputum on most days for at least 3 months of the year for at least 2 consecutive years. A detailed description of cough frequency, sputum volume, color, and consistency should be obtained, as should a determination of whether there are any specific precipitating factors. It is important to remember that intermittent cough, with or without sputum production, is a relatively common presenting complaint of asthma. Wheezing and chest tightness should also be described in terms of frequency, time of occurrence, whether there is seasonal variation, precipitating factors, and whether there is associated dyspnea that limits ability to function.

A comprehensive medical history, including hospitalization, allergies, and medications, should be obtained, so that conditions other than respiratory diseases that contribute to or modify any impairment present can be identified. A detailed history of the applicant's employment in chronological order is required for both attribution and disability evaluation purposes. Questions about actual job activities in addition to job titles are useful. Specific information about occupational exposures to dust, gases, and fumes is required, including the identification of the agent (generic or brand name, or both), the time of onset, intensity, and duration of exposure, the patient's estimate of the hazard of

Table 30–7. Components of Respiratory Impairment Evaluation

1. Clear understanding of the requirements of the agency requesting the evaluation
2. Complete medical history (including an occupational and environmental exposure history)
3. Physical examination
4. Laboratory tests
   - A. Tests directed at identifying extrapulmonary condition contributing to impairment: complete blood count, electrocardiogram
   - B. Tests directed at the assessment of respiratory impairment
     - i. Chest roentgenogram
     - ii. Spirometry
     - iii. $D_{LCO_{sb}}$ (single breath diffusing capacity)
     - iv. Pulmonary exercise test (not always required)
     - v. Arterial blood gas measurements (not always required)
5. Diagnoses/interpretation
   - A. Attribution to work (if requested)
   - B. Determination of clinical stability (e.g., "permanent and stationary") for rating purposes
6. Impairment rating
   - A. Specific work preclusions/accommodations
   - B. Assessment of need for future treatment

the exposure, and the duration of time since the exposure ceased. A Material Safety Data Sheet (MSDS) for each potentially hazardous material in the workplace should be available from the patient's employer, and these forms may be helpful in the identification of significant occupational exposures. If the patient is still working, his or her current job needs to be well characterized in terms of physical exertion requirements (both average and peak), emergency needs, exposures to respiratory tract irritants, availability of respiratory protective equipment, and possibilities for job accommodations.

Inquiries should be made into avocational activities to uncover any potential contributing exposures such as could occur with automobile restoration, furniture refinishing, or pigeon breeding. The home environment should be characterized regarding the presence of pets, environmental tobacco smoke, humidifiers, wood-burning stoves, etc. A detailed smoking history must be obtained, including the age at which the patient started to smoke, estimates of both the average and maximum amount of tobacco smoked per day, and if and when smoking was stopped. The cumulative dose of cigarette smoke exposure should be characterized in terms of "pack-years" (i.e., the number of packages smoked per day times the number of years of smoking). Although a sensitive area around which there are confidentiality concerns, questions about past or current use of recreational drugs should also be asked. One should remember that, in workers' compensation cases, the employer or the employer's representatives may have access to an applicant's complete medical records. Information about avocational, environmental, and tobacco smoke exposure is especially important when the evaluating physician is being asked to give an opinion on the apportionment of causation of respiratory impairment.

Table 30–8. American Medical Association Classification of Dyspnea*

Mild	Dyspnea is present with fast walking on level ground or walking up a slight hill; the person can keep pace with other persons of same age and body build on level ground but not on hills or stairs.
Moderate	Dyspnea is present while walking on level ground with persons of the same age and body build or walking up one flight of stairs.
Severe	Dyspnea is present after the person walks more than 4 to 5 minutes at own pace on level ground; the person may be short of breath with less exertion, or even at rest.

*Modified with permission from the American Medical Association: Guides to the Evaluation of Permanent Impairment, 3rd rev. ed. Chicago, American Medical Association, 1991.

Physical Examination

The examining physician should perform a complete physical examination with special emphasis on the respiratory and cardiovascular systems.[8, 9] The general description of the patient should include observations about the degree of breathing difficulty at rest and with walking on level ground or climbing steps. Blood pressure, pulse, and respiratory rate should be measured, preferably by the examining physician. A detailed description of the chest examination is required, including the results of inspection, percussion, and auscultation.

The character of adventitious breath sounds should be described during both resting tidal breathing and slow, deep breaths. The relative duration of inspiration and expiration should be noted. Any wheezing, rhonchi, or crackles should be described as to intensity, location, and phase of the respiratory cycle. If late-inspiratory crackles are heard posterolaterally at the lung bases, then it is important to check for their persistence following coughing before recording this finding as evidence of pulmonary interstitial fibrosis.

The examining physician should look for evidence of pulmonary hypertension, cor pulmonale, and right heart failure. The presence or absence of clubbing of the fingers and toes should be noted, as well as cyanosis of the buccal mucosa, lips, and nail beds.

The physical examination is probably more useful for detecting signs of non-respiratory organ system dysfunction that could be contributing to disability than for characterizing the level of respiratory impairment. An exception is when there is evidence of end-stage disease, such as cyanosis or right heart failure, which does provide support for a severe respiratory impairment rating.

Laboratory Tests

Tests Directed at Identifying Extrapulmonary Conditions Contributing to Impairment. A complete blood count may detect anemia that can be causing or contributing to an applicant's complaint of dyspnea on exertion. Erythrocytosis secondary to chronic hypoxemia may also be detected. An electrocardiogram can identify abnormalities consistent with ischemic heart disease or left ventricular hypertrophy that suggest a possible cardiac component to the applicant's impairment. The presence of cor pulmonale may also be suggested by electrocardiographic evidence of right atrial or ventricular hypertrophy, or both. Further cardiac work-up with echocardiographic or radionuclide studies may be warranted. Evidence of left ventricular failure on chest roentgenograms should also be noted.

Tests Directed at the Assessment of Respiratory Impairment. *Chest Roentgenogram.* The chest roentgenogram is more useful in determining the etiologic diagnosis rather than the level of impairment. Chest roentgenographic findings generally correlate poorly with physiologic findings in patients with obstructive lung disease. With some diffuse interstitial diseases such as asbestosis, roentgenographic findings may correlate better with physiologic findings, but a sizable fraction of patients with histologically confirmed interstitial fibrosis have normal chest roentgenograms. Despite these caveats, review of the chest roentgenogram is still considered to be an essential element of a respiratory impairment evaluation, and any abnormalities should be described carefully.[8, 9] If the applicant is suspected of having a pneumoconiosis (e.g., silicosis, coal workers' pneumoconiosis, or asbestosis), then the chest roentgenogram should be classified according to the International Labour Organisation scheme by a qualified reader.[48]

Pulmonary Function Tests. The pulmonary function tests that are most useful in the evaluation of respiratory impairment are those that have high predictive value or validity regarding the applicant's ability to tolerate exercise. Evaluation of pulmonary function at rest and during exercise is discussed in detail in Chapter 28.

An expert committee of the ATS has recommended an approach to the evaluation of respiratory impairment that does not require pulmonary exercise testing for most applicants.[8] The ATS approach emphasizes spirometry and the single-breath diffusing capacity for carbon monoxide (DL_{CO}). Ideal tests of respiratory impairment have the following features: wide availability, acceptability to most patients and lack of substantial risk, simplicity of performance according to a standardized protocol, reproducibility, relative insensitivity to an applicant's motivational state, and the capability of detecting a wide range of abnormalities of the respiratory system. The ATS expert panel selected spirometry and DL_{CO} as the primary tests of respiratory impairment because these tests meet most of these criteria. A major controversy, however, is whether the correlation between either FEV_1 or DL_{CO} and $\dot{V}O_2$/exercise tolerance in patients with chronic obstructive and diffuse interstitial lung diseases is adequate to allow the rating of impairment in most patients without exercise testing.[27, 28, 32, 49]

Except for FVC, lung volumes show poor correlation with exercise tolerance. Tests of so-called small airway function are too variable to be useful in respiratory impairment evaluation, and their limitations are discussed in Chapter 28. Lung compliance is difficult to perform, is poorly tolerated, and has not been well-correlated with exercise tolerance. The MVV test is not recommended for routine use in respiratory impairment evaluation for multiple reasons; it involves a larger learning effect, is more fatiguing, and requires better instrumentation than simple spirometry. The Social Security disability rating scheme, however, mandates the use of the MVV (and FEV_1) in the rating of impairment due to chronic airflow obstruction.[43] With interstitial lung disease, the MVV may be normal even when there is a severe impairment of gas exchange.

Spirometry should be performed on properly calibrated equipment that meets ATS specifications and following ATS performance criteria.[38] If airflow obstruction is present, spirometry should be repeated after the administration of inhaled bronchodilator. The prediction equations for FEV_1 and FVC recommended in the 1986 ATS statement on respiratory impairment evaluations are those of Crapo and co-workers.[40] There is no evidence that the use of the Crapo reference values provides any benefit over the use of other established reference populations, and, in fact, the Black Lung Benefits Program mandates the use of the Knudson equations.[47] An empirical study has shown that the use of prediction equations for spirometric parameters other then those of Crapo will have only a small effect on the impairment rating.[50] In contrast, the method of calculating DL_{CO} predicted values (and correcting for alveolar volume) can greatly affect the rating. All of the predicted equations commonly used by pulmonary function laboratories in the United States are derived from studies of Caucasian populations. Although studies have repeatedly demonstrated racial and ethnic differences in the predicted values for FEV_1 and FVC, there is no consensus on what correction factor should be applied for persons of various racial and ethnic groups. The AMA recommends a correction factor of 10% for persons of African or Asian descent (i.e., multiply Caucasian predicted values by 0.9)[9] and many computerized spirometers automatically correct predicted values by this value when a nonwhite racial category is selected. It is important to know what predicted values the individual laboratory is using and whether any routine adjustment for race is being applied, as well as to indicate this information in the evaluation report. Harber[51] has documented that the use of the per cent of predicted approach to impairment rating recommended by both the AMA and ATS has an inherent bias in favor of rating older and shorter persons as impaired. The approach also does not take into account residual lung function. An injury leading to a loss of 1 L of FEV_1 is assumed to have the same effect whether it leaves a residual FEV_1 of 1 L or 3 L.

The single-breath diffusing capacity is a test prone to substantial inter- and intralaboratory variability and thus must be performed carefully according to ATS performance criteria.[39] Measurement of DL_{CO} is affected by factors other than respiratory disease, including hemoglobin concentration and altitude, but the effects of extrapulmonary factors are usually smaller than the variability of the test itself. When the results of DL_{CO} measurements are corrected for severe anemia or erythrocytosis, the ATS recommends that the uncorrected values be reported as well. For predicted values for DL_{CO}, the ATS recommends use of Crapo and Morris[41] regression equations, normalized to a standard hemoglobin concentration of 14.6 g/dL for men and 12.8 g/dL for women. Because of the inherent variability of DL_{CO}, a good-quality assurance program for this test is essential for every pulmonary function laboratory.

As noted above, it was the view of the ATS expert panel that the respiratory impairment of most patients can be categorized on the basis of spirometry and DL_{CO}.[8] Again, this depends on whether the evaluating physician is being asked to determine if loss of function has occurred or whether the patient can perform some level of work. Spirometry and DL_{CO} usually suffice to answer the former question, but exercise testing is often needed to answer the latter.

Arterial Blood Gas Measurement. Resting arterial PO_2 does not correlate with exercise capacity. As a result, arterial hypoxemia at rest is, by itself, not evidence of severe impairment. The ATS statement treats resting arterial hypoxemia as a "modifying condition," e.g., in a patient whose spirometry and DL_{CO} results straddle the border between two categories of impairment, the presence of a low arterial PO_2 can justify a rating of the higher category of impairment.[8] Because of the variability of arterial blood gas measurements even in stable patients, arterial hypoxemia should be documented by at least two measurements at least 4 weeks apart. Most patients who develop hypoxemia with exercise as a consequence of respiratory disease show evidence of impairment on spirometry or DL_{CO}.[52]

Exercise Testing. Pulmonary exercise testing with direct measurement of $\dot{V}O_{2max}$ provides quantitative data regarding the patient's capacity for work.[28, 32, 53] Although exercise testing is now more widely available and commonly used than when the ATS expert panel was putting together its recommendations, it is still not necessary in every respiratory impairment evaluation. The ATS recommends exercise testing only for those cases where spirometry and DL_{CO} may have underestimated the level of impairment.[8] If resting lung function is severely impaired (and usually if it is normal), exercise testing is not required. In our opinion, however, patients with less than severe impairment on static lung function tests will often need to be further evaluated by exercise testing, especially if the primary question is whether or not they are disabled for a given job.[32]

An argument for exercise testing is that because $\dot{V}O_2$ can be measured and tables are available to relate the measured value to the energy requirements of various types of employment, impairment evaluation is thus rendered more objective and straightforward. If a patient cannot consume sufficient oxygen to perform the work required by his or her job because of physiologic abnormalities, then cardiopulmonary impairment is present that can be considered disabling. Another advantage of exercise testing is that the patient's level of performance can be directly observed. If the patient does not achieve a heart rate approaching the maximal predicted value and/or reach the anaerobic threshold during a maximal, symptom-limited exercise test, then lack of effort should be suspected. Finally, in patients whose exercise intolerance is suspected of having a multifactorial origin, exercise testing allows assessment of the relative contributions of respiratory and non-respiratory causes (e.g., cardiac disease and physical deconditioning). For this purpose, calculation of $\dot{V}O_2$ from the direct measurement of oxygen concentration in mixed expired gas and minute ventilation is preferred over estimates from power output or heart rate, or both.

There is some debate over whether maximal, symptom-limited exercise testing is essential for evaluating work capacity.[7, 8, 32, 53, 54] Although the ATS currently recommends a maximal test if exercise testing must be performed,[8] it can be argued that submaximal exercise testing is better tolerated, safer, easier to perform, and thus more widely applicable in respiratory impairment evaluation. There is no question that useful information can be obtained from submaximal testing, such as whether or not a patient can achieve a predetermined workload. Submaximal testing with direct measurement of $\dot{V}O_2$ also can provide information about the relative efficiency of the respiratory and cardiac systems during exercise.

The major disadvantage of submaximal testing is that maximum work capacity is not determined. To overcome this limitation, several schemes have been developed to derive an estimated $\dot{V}O_{2max}$ from data generated at submaximal effort.[55–60] Because of the essentially linear relationship among $\dot{V}O_{2max}$, heart rate, and ventilation, either of the latter two parameters can be used to estimate the former. Alternatively, Jones[53] has proposed using the Wick graph to estimate maximal oxygen consumption from power output on either a cycle ergometer or a treadmill.

Weller and co-workers[54] have documented that the relation of cardiac frequency to $\dot{V}O_2$ during progressive submaximal exercise can be used to predict exercise capacity in young (ages 23 to 47 years), healthy shipyard workers by extrapolation to the predicted maximal heart rate. These investigators cautioned, however, that this method is more applicable to fitness for duty assessment than to respiratory impairment/disability evaluation, because anxiety-related hyperventilation and/or tachycardia may produce an artificially low estimated $\dot{V}O_{2max}$. Some authors have argued that a prediction equation for $\dot{V}O_{2max}$ that includes fat-free mass and FEV_1, in addition to minute ventilation, tidal volume, and cardiac frequency at submaximal exercise (i.e., $\dot{V}O_2$ of 1 L/min), provides a more accurate basis for respiratory impairment evaluation than the primary ATS approach of using spirometry and DL_{CO} results without requiring maximal, symptom-limited exercise testing in all patients.[6, 61]

Once $\dot{V}O_{2max}$ has been directly measured or estimated, this volume can be used to determine the patient's capacity for various types of work based on published lists of energy requirements for specific jobs.[30, 62–65] The ATS statement recommends three categories of impairment based on $\dot{V}O_{2max}$, and this recommendation has been accepted by the AMA.[8, 9] An explicit assumption of the ATS/AMA rating scheme is that patients can work comfortably at approximately 40% of their $\dot{V}O_{2max}$. If the maximal oxygen consumption is greater than or equal to 25 mL/kg per min (7.1 metabolic equivalents [METS], defined as the energy demand in liters of oxygen consumption per minute/basal oxygen consumption [3.5 mL/kg per minute]), then the patient should be capable of continuous heavy exertion throughout an 8-hour shift and would be limited in only the most physically demanding jobs. When the $\dot{V}O_{2max}$ is between 15 and 25 mL/kg per minute, then the energy requirements of the job must be assessed. If the average energy requirements of the work are less than 40% of the patient's $\dot{V}O_{2max}$, then the patient should be able to work comfortably for a full shift on the job. An exception would be a job that requires frequent periods of exertion at workloads substantially greater than 40% of the patient's $\dot{V}O_{2max}$. The ATS target work capacity may be a bit ambitious for many patients. Some investigators suggest that an individual can tolerate only 8 hours of work at 35% of his $\dot{V}O_{2max}$.[31] Patients with a $\dot{V}O_{2max}$ less than or equal to 15 mL/kg per minute (4.3 METS) are considered unable to perform most jobs and are then rated severely impaired. The average energy requirements of a number of jobs are listed in Table 30–9.

The ATS scheme assumes that accurate information about the energy requirements of the patient's job is available. Many factors may modify either the $\dot{V}O_2$ required for a given job or the physiologic stress associated with working at that level of anaerobic power.[49] Although the energy requirements for jobs can be broadly categorized, the specific requirements for the individual patient's job and that person's ability to tolerate this level of work can be accurately assessed only from direct measurements on the job or by closely simulating actual work conditions in the laboratory. Although data are available for the energy requirements of a broad range of work activities, many of these data are quite old and specific information about current job demands in modern workplaces is often lacking.[30, 62–65] A 1986 workshop sponsored by the National Heart, Lung, and Blood Institute identified this area as an important focus for future research.[6]

With a maximal, symptom-limited test, it is important to determine whether exercise was limited by respiratory impairment. Some questions to consider in this regard are the following: Was exercise terminated because of non-respiratory symptoms (e.g., fatigue, chest pain, leg pain)? Was a low breathing reserve ($FEV_1 \times 35$ − measured minute ventilation) present at termination of exercise?[53] Was there hyperventilation, especially of a variable nature, at submaximal workloads? Was the patient's anaerobic threshold achieved?

Special Considerations for Specific Types of Respiratory Impairment

Chronic Airflow Obstruction. Patients with severe chronic airflow obstruction often have a ventilatory limitation to exercise that may cause them to be unable to work in jobs requiring significant levels of exertion. The results of spirometry (especially FEV_1) usually correlate fairly well with the degree of exercise limitation in large groups of patients with moderate to severe airflow obstruction.[22, 66, 67] Because there is a fairly wide scatter in these group data, however, the predictive value of spirometry for an individual patient is not particularly high. Symptoms associated with chronic airflow obstruction may make work in certain jobs difficult even in the absence of significant ventilatory limitation. For example, a patient with chronic bronchitis who has frequent cough productive of large amounts of sputum would be unable to wear a respirator without having to remove it periodically in order to expectorate. Because the patient presumably is required to wear the respirator as protection from an inhalational hazard in the workplace, the

Table 30–9. Energy Requirements of Various Types of Work*

Level of Work	$\dot{V}O_2$ (approximate) mL/kg/min	$\dot{V}O_2$ (approximate) L/min	METS†
Light to moderate work (sitting)			
Clerical	5.6	0.42	1.6
Using repair tools	6.3	0.47	1.8
Operating heavy equipment	8.8	0.66	2.5
Heavy truck driving	12.6	0.95	3.0
Moderate work (standing)			
Light work, own pace	8.8	0.66	2.5
Janitorial work	10.5	0.79	3.0
Assembly line (lifts 45 lb. +)	12.3	0.92	3.5
Paper hanging	14.0	1.05	4.0
Standing and/or walking (arm work)			
General heavy labor	15.8	1.19	4.5
Using heavy tools	21.0	1.58	6.0
Lift and carry 60–80 lb.	26.2	1.97	7.5

*Modified with permission from Becklake, M.: Organic or functional impairment. Am. Rev. Respir. Dis. 121:647–659, 1980.
†METS, the energy demand in liters of oxygen consumption per minute/basal oxygen consumption (3.5 mL/kg per minute).

person is effectively precluded from working in this job.

Irrespective of the level of impairment based on resting pulmonary function, a patient with chronic airflow obstruction who has evidence of cor pulmonale should be rated as severely impaired.[8, 9]

Asthma. The 1986 ATS statement was primarily focused on patients with chronic respiratory disorders associated with irreversible tissue damage and relatively fixed functional deficits. Asthma was considered a "modifying condition." A patient with asthma was considered severely impaired by the 1986 ATS approach if the patient required admission or emergency room treatment for attacks of bronchospasm six or more times per year *and* prolonged expiration with wheezing or rhonchi was present between attacks despite optimal therapy.[8] Unfortunately, many patients with severe asthma who are disabled from working in the jobs for which they are trained do not meet these criteria. Physicians experienced in the treatment of asthma try to prevent frequent attacks of bronchospasm with daily medication, including high-dose inhaled or oral steroids, so that six attacks requiring emergency room treatment per year are unlikely even for a patient with severe asthma.

Chan-Yeung[68] was perhaps the first to point out that asthma is a condition with features that the 1986 ATS approach to respiratory impairment/disability evaluation inadequately addresses. Asthma is characterized by variable airflow obstruction, and an asthmatic patient's clinical status may change over time. Airflow obstruction is partially or completely reversible with appropriate therapy, so lung function may be normal at the time of evaluation. The condition is characterized by airway hyperresponsiveness to irritants such as dusts, fumes, gases, or smoke that often renders asthmatic patients unable to work in certain environments.

Because of these special features of asthma, an ATS committee recently developed a new set of guidelines for the evaluation of impairment/disability in patients with this condition.[42] These guidelines take into consideration the degree of airway hyperresponsiveness and the type and amount of medication required to control asthmatic symptoms in addition to evidence of airflow obstruction by spirometry. Measurement of DL_{CO} is not required and is recommended only to distinguish asthma from other conditions.

The new ATS guidelines recognize that impairment/disability due to asthma may be either temporary or permanent.[42] Temporary impairment is used to describe a patient's status that is expected to improve in the future with avoidance of trigger factors or optimal therapy, or both. Permanent impairment describes a patient's status when improvement has been maximal on optimal medical management. A permanent impairment rating should not be given until the following objectives of treatment have been achieved: control of asthma or best overall results as defined by least symptoms, need for bronchodilator if taken only as needed, airflow obstruction by spirometry, diurnal variation of peak expiratory flow rate, and medication side-effects; use of minimum medication to maintain control or best overall results; identification and avoidance of trigger factors; and early treatment of exacerbation to prevent severe attacks of bronchospasm. If these objectives have not been achieved, then a temporary impairment rating should be given *and* specific recommendations made for management or referral to a physician experienced in the management of asthma. The patient should be re-evaluated when the objectives of treatment have been achieved or in 6 months, whichever is shorter. Because asthma may improve or worsen with time, it may be necessary to re-evaluate the patient if the clinical status changes even after a "permanent" disability/disability rating has been given.

The new ATS approach for the evaluation of respiratory impairment/disability in asthma involves a three-category rating scheme (see Table 30–2).[42] Total impairment (Class V) is defined as asthma that cannot be controlled adequately, i.e., despite maximal treatment, including 20 mg or more per day of oral prednisone, the FEV_1 remains less than 50% of predicted.

Further considerations must be applied to patients with occupational asthma due to a sensitizing agent. Multiple longitudinal follow-up studies document that the majority of patients with sensitizer-induced occupational asthma fail to completely recover after cessation of response to the offending agent.[68] Early diagnosis and cessation of exposure have been shown to improve the prognosis for recovery. In contrast, continued exposure to the offending agent can lead to clinical deterioration and even death due to acute bronchospasm.[69]

After a diagnosis of occupational asthma due to a sensitizing agent has been made, the appropriate treatment is to remove the worker from further exposure. Patients with sensitizer-induced occupational asthma should be considered 100% impaired on a permanent basis for the job that involves exposure to the causative agent as well as for other jobs with exposure to the same agent.[8, 9, 42]

Interstitial Lung Disease. A study of over 800 patients with interstitial lung disease conducted by Epler and co-workers[16] indicated that resting spirometry and DL_{CO} were reasonably good predictors of dyspnea on exercise.[16] Resting lung function did not correlate as well with either histologic severity of disease or ventilatory parameters (e.g., the ratio of ventilation to either $\dot{V}O_2$ or MVV) during exercise. In most patients with chronic airflow obstruction, ventilatory efficiency typically improves with exercise; in contrast, patients with interstitial lung disease tend to develop decreased ventilatory efficiency, an increased dead space to tidal volume ratio, and an increased alveolar-arterial oxygen tension difference with exercise. As a result, exercise testing may play a larger role in the evaluation of impairment in patients with interstitial lung disease than in those with chronic airflow limitation.

Occupationally induced interstitial lung disease, or pneumoconiosis, presents a special problem for impairment evaluation. The diagnosis of a pneumoconiosis may create an impairment despite normal lung function because further exposure to the causative agent may increase risk of progression.[8, 9] Unlike the situation with sensitizer-induced occupational asthma, however, the preclusion from further exposure is relative rather than absolute. For example, a sheetmetal worker with mild asbestosis due to heavy exposure in the past may be able to continue working under current conditions provided he is able to wear proper respiratory protective equipment when necessary.

With hypersensitivity pneumonitis (extrinsic allergic alveolitis), however, continued exposure to the offending agent is likely to lead to either acute attacks or insidious progression of disease, depending on the dose of exposure. Therefore, patients with hypersensitivity pneumonitis should be considered 100% impaired on a permanent basis for any job that involves future exposure to the causative agent.[8, 9]

Other Respiratory Disorders. Upper airway obstruction can cause respiratory impairment that may not be adequately assessed by the evaluation scheme outlined above. The 1986 ATS statement indicates only that impairment due to upper airway obstruction should be considered severe if carbon dioxide retention is present.[8]

With sleep apnea, there are two major considerations. First, patients with sleep apnea may have daytime hypersomnolence that impairs their ability to perform certain potentially dangerous jobs like driving motor vehicles or operating heavy machinery. Second, chronic nocturnal hypoxemia as a result of sleep apnea can lead to pulmonary hypertension and cor pulmonale. If cor pulmonale is present, then the impairment is severe.[8]

Like sleep apnea, cough syncope is a cause of impairment because of the potential for loss of consciousness.[8]

Patients with bullae in the lung are at increased risk of developing spontaneous pneumothorax from barotrauma and are therefore unable to work in jobs involving deep sea diving and high-altitude flying.

Assessment of Job Requirements

Although the AMA and ATS classification schemes for respiratory impairment/disability are focused on deviation from normality with regard to resting lung function test results, the assessment of residual work capacity may be of greater importance for a given patient's ability to perform a specific job. For example, an asbestos insulator with a moderate impairment by the AMA/ATS classification might not be able to tolerate the exertion required by the job, but might have sufficient residual capacity to perform less physically demanding work. Proper determination of work fitness involves assessment of both the patient's functional capacity and the requirements of the job.[2, 32, 49] The evaluating physician's ability to assess functional work capacity through increasingly sophisticated exercise testing is usually considerably greater than the ability to characterize specific job requirements.

As already noted, standard references list the energy requirements in METS or mL/kg per minute of various occupations and the evaluating physician can relate the patient's $\dot{V}O_{2max}$ to the value listed for a given job.[30, 62–65] Unfortunately, there are a number of problems with this approach.[70, 71] First, very few jobs have been adequately studied and where information exists, it may be outdated and irrelevant to current, highly mechanized work practices.[72] Second, occupations are frequently listed in broad categories, and patient job titles may be relatively nonspecific. For example, "machine operator" work may involve activities ranging from those requiring very light exertion to those requiring heavy lifting. The energy requirements listed for an occupation are typically those of an "average" worker on an average day. Actual $\dot{V}O_2$ measurements at the workplace are made by either collecting mixed expired gas from workers or using a mask and oxygen analyzer system. Both of these methods may interfere with the performance of work and thereby lead to misclassification of job energy requirements. On the other hand, if the work situation is simulated in the exercise laboratory to avoid inaccuracies of field measurements, the validity of the more "accurate" laboratory measurements becomes an issue. The use of impedance plethysmography to measure minute ventilation and ventilatory rate has been suggested as an alternative, less obtrusive approach to the assessment of job specific energy requirements at the workplace.[49]

Another relatively unobtrusive technique of estimating $\dot{V}O_2$ during work is the use of continuous heart rate monitoring devices. This technique can be an effective surrogate for direct measurements but is affected by many factors. Cardiac frequency, as noted previously, is linearly related to $\dot{V}O_2$, except at very low or very high levels of exertion. The slope of the relationship may differ substantially among individuals, however, with fit individuals demonstrating a larger increase in $\dot{V}O_2$ for any increase in heart rate than a less fit person. Anxiety, dehydration, heat stress, alcohol use, and arm work will all increase heart rate without a concomitant increase in oxygen consumption.[73, 74] Several teams of investigators have used continuous heart rate monitoring at the work site coupled with exercise testing in the laboratory to calibrate the heart rate–oxygen consumption relationship in an effort to improve the quality of the field data.[72, 74–75] In one such study of coal miners by Harber and co-workers,[72] energy expenditure varied significantly among workers with the same job title, with younger workers spending more time at higher levels of exertion than older workers. The median estimated $\dot{V}O_2$ for the coal miners was 3.3 METS, but 10% of the time the energy requirements were 6.3 METS.

One coal miner in the study by Harber and coworkers[72] was apparently able to perform this moderate-to-heavy work without symptoms despite an FEV_1 of 46% of predicted, a level that would have rendered him moderately impaired by the AMA/ATS classification scheme and totally disabled under the Black Lung Benefits Program. This example highlights the complexity of job-specific disability evaluation. Ideally, multiple factors should be considered, and they are listed in Table 30–7. Particular attention needs to be paid to job accommodation because under the Americans with Disabilities Act, employers are required to make "reasonable" efforts to restructure a disabled worker's job through part-time or modified work schedules, reassignment, acquisition of mechanical assist devices, modification of equipment, etc., to permit the worker to perform the "essential" aspects of the job. Whether respiratory protective equipment is required is another important consideration and clearance for respirator use will be discussed in detail.

Final Assessment and Report

The evaluating physician's assessment of a patient's respiratory impairment/disability must be thoroughly justified in a written report that includes the appropriate history, physical findings, and laboratory data. Although various entitlement or compensation programs may require that specific questions be answered, a general approach to the impairment/disability evaluation report is outlined below.

It is wise to begin the assessment or discussion section of the report with a brief summary of the patient, especially if the complete history is long and complicated. Many claims representatives/adjustors, attorneys, and/or administrative law judges will skip the history, physical examination, and laboratory data sections of the report and will start reading at the assessment or discussion section. Next, the patient's diagnosis should be stated clearly, and the evidence that supports these diagnoses should be summarized. For a workers' compensation evaluation of potentially work-related lung disease, the degree of certainty that the disease has been caused or aggravated by occupational factors must also be stated. It is important to remember that workers' compensation systems require a degree of medical certainty, i.e., "more probable than not," that is less rigorous than would be required for scientific proof of a hypothesis.

The term *attribution* is used to describe the process by which the evaluating physician determines whether a given workplace exposure has caused or aggravated an illness.[44] Attribution in cases of respiratory illness may be difficult because of multifactorial causation, frequently a long latency between initial exposure and clinical onset of disease, nonspecific clinical presentations, incomplete understanding of dose-response relationships from epidemiologic studies, and lack of individual exposure data. Although recognition of these limitations is necessary, causation can be attributed in most cases on a more probable than not basis by simply applying reasonable judgment. For example, in a patient with interstitial pulmonary fibrosis, what is the probability that the disease is asbestosis rather than a process that is not work-related? If the patient was exposed to visible asbestos dust on most work days for more than 10 years as a shipyard boilermaker and more than 20 years have elapsed since the onset of exposure, it is more probable than not that the patient's interstitial fibrosis is due to the occupational exposure to asbestos dust. On the other hand, if the patient is a school teacher who has been working for the past 5 years in a classroom through which an asbestos-insulated steam pipe passes and has been exposed only to the small amounts of asbestos dust that have emanated from a crack in the insulation, then it is unlikely that the interstitial fibrosis is asbestosis. Attribution here is based on the likelihood of asbestosis vs. competing diagnoses. Among workers heavily exposed to asbestos, the prevalence of asbestos-related fibrosis is high, whereas the prevalence of non-occupational interstitial fibrosis in the general population is quite low. The school teacher, however, cannot be considered to have been exposed to a significant dose of asbestos, nor has there been a latent period of sufficient duration. Attribution is easier when the exposure is known, the dose-response relationship is well characterized, and competing diagnoses are unlikely. When one or more of these conditions are not met, attribution should be based on the answers to the following questions:

(1) Is the diagnosis clearly established, and is it biologically plausible (or consistent with the available epidemiologic data) that the disease could have been caused or aggravated by the exposure in question?

(2) Have competing diagnoses been adequately considered?

(3) Is the exposure of sufficient intensity and duration to have caused or aggravated the disease?

(4) Has there been an adequately long latent period, or is there a temporal relationship between onset of exposure and clinical manifestation of disease?

As difficult as attribution may be for the evaluating physician, *apportionment* raises even thornier issues.[51] Apportionment is the process by which the relative contributions of multiple diseases and/or multiple causes of diseases are separated and rated with regard to the overall impairment. Attorneys and claims adjustors generally seek to have precise percentages ascribed to the amount of impairment that results from a specific disease or cause of disease for purposes of calculating the dollar value of compensation or benefits. Unfortunately, the scientific basis for this level of precision is rarely present.

In evaluation of impairment due to respiratory disease, the effects of cigarette smoking are the most common reason that apportionment is necessary. For example, in a patient who worked as a welder for 40 years and also had a 40 pack-year smoking history, how does one apportion his moderate impairment due to chronic airflow obstruction? Is 30% of his impairment a result of occupational exposure to welding fumes with 70% due to smoking? Or is the correct apportionment 50% to each factor? It is hard to defend percentage apportionments unless good exposure-response data are available, including the additive or synergistic effects of cofactors. Even then, is it appropriate to apply population-derived data to an individual case? Although cigarette smoking has clearly been established as a cause of chronic airflow limitation through epidemiologic studies, most people who smoke do not develop significant impairment. Inhalation of welding fumes is generally considered to be irritating to the respiratory tract, but there are inadequate epidemiologic and toxicologic data available on dose-response to guide the evaluating physician's attempt at apportionment. If there is an interactive effect of cigarette smoke and welding fume exposures, is it additive or synergistic? Given the degree of uncertainty concerning the true biologic effects of these two exposures on this patient's impairment, it is better to make a reasoned judgment about their relative contributions, based on the history, objective findings, medical record review, and one's training and experience, than to guess at what percentage is due to each factor. An appropriate statement might be the following: "Although a substantial portion of this patient's present impairment would probably have existed anyway as a result of the natural progression of obstructive lung disease due to cigarette smoking, the occupational exposure to welding fumes is an aggravating factor that likely made the total impairment more severe than it otherwise would have been."

Apportionment is somewhat easier when there are objective findings that allow the effects of different exposures or diseases to be distinguished. In a patient with asbestosis who has a long smoking history, for example, the presence of a mixed obstructive-restrictive pattern provides evidence that both the asbestosis and chronic airflow obstruction due to cigarette smoking are contributing to the total impairment. In another patient with asbestosis, exercise test results show evidence of both a ventilatory limitation and ischemic changes on electrocardiographic monitoring. This patient's total impairment should be apportioned between that which results from asbestosis and that which is due to ischemic heart disease.

Although epidemiologic data on exposure-response relationships and/or distinguishing objective findings, when available, can be of assistance in the apportionment process, the evaluating physicians must typically rely on their clinical judgment.

RESPIRATOR CLEARANCE

A major component of impairment assessment involves clearing workers as being "fit for duty." This often involves an assessment of their ability to wear personal protective equipment while performing the required activities of the job. For some, protective equipment will include heavy boots, protective clothing and gloves, as well as some form of respirator. Such equipment can place an added load on the pulmonary and cardiovascular systems due to factors such as weight, resistance to movement, and heat stress.[76–86] For most workers needing respirator clearance, however, usual work clothes will be worn.

Clearance for respirator usage is generally a yes or no decision. The recent implementation of the Americans with Disabilities Act, however, will increasingly require consideration of job modifications for those who cannot be cleared for respirator usage without reservation. In addition, physicians should be aware of the discomfort associated with respirator usage[87–93] and consider whether other methods to reduce exposure such as improved ventilation or product substitution can eliminate the need for respirator usage.

Unlike the yes or no answer expected from an employer regarding a patient's ability to wear a respirator, criteria for clearance are unfortunately not straightforward.[90, 94–96] Respirator usage may result in increased work of breathing[76–79, 82–86] and, as is the case with heavy protective equipment such as a self-contained breathing apparatus (SCBA), may result in increased energy requirements.[97–99] Evaluating patients for respirator clearance is, at best, an uncertain art. The major areas of uncertainty involve the estimation of the energy requirements in all aspects of a job (including peak and emergency needs),[71, 72] the incremental increased work of breathing from the respirator, and the maximal and submaximal exercise capacity of the patient in the absence of a formal exercise test. These uncertainties result in wide confidence intervals in predicting who can or cannot wear a respirator.

One crude rule of thumb for clearance to use a respirator is that if the patient is currently able to do the job without symptoms, the person is likely to be able to do the job while wearing a respirator. The justification for this rule is that most respirators add little to the work of breathing. Crude as this rule is, guidelines for respirator clearance that promise more precision must be viewed with skepticism. Given the various uncertainties in clearing workers for respirator usage, the evaluating physician must recognize that the application of stringent criteria may increase the likelihood that cleared workers will have adequate lung function and exercise capacity to use a respirator (low rate of false-positive clearance), but will also discriminate more often against those who, failing to meet the criteria, could actually still perform the job while wearing a respirator (high false-negative rates). Conversely, less stringent criteria will have the opposite effect.

Types of Respiratory Protective Devices

Respirators can be categorized into two major categories: negative-pressure and positive-pressure devices.

Negative-Pressure Respirators. Negative-pressure (or "demand") respirators simply consist of a tight fitting mask and a filter through which air is drawn on inhalation. Exhalation is usually via a low-resistance expiratory valve. Physiologically, negative-pressure respirators increase the work of breathing because of an increase in dead space and because of the resistance associated with drawing air through a filter.[76–79, 84–86] The increased work of breathing depends on the minute ventilation and the fixed resistance of the filter. Studies of negative-pressure respirators have shown reductions in the MVV and FEV_1 to be less than 10%.[100] In general, the effects of negative-pressure respirators on dead space and increased work of breathing are relatively small.[101] Thus, there is little resultant reduction in work capacity. A patient who becomes ventilation-limited in the course of performing a job, however, may have difficulty wearing a negative-pressure respirator.

Positive-Pressure Respirators. Positive-pressure respirators come in essentially three forms: SCBAs, air-supplied respirators, and air-purifying respirators. All are characterized by a relative lack of increased resistance to inhalation.[102–107] The use of a SCBA may involve some increased work of breathing associated with inspiration and expiration, but the major consideration is the ability of the worker to carry the additional weight of the device (approximately 35 lb.) while performing the job.[96] Despite this limitation, the SCBA provides a high protective factor against the inhalation of airborne contaminants in relatively toxic atmospheres such as those encountered in fire fighting. Powered air-purifying respirators and air-supplied respirators are associated with far less problems, do not result in increased dead space, weigh relatively little, and provide a substantial protective factor in less hazardous environments.

Procedures for Respirator Clearance

Respirator clearance must take into account several job-related and patient-related factors. The job-related factors are the average and maximum energy requirements, the type of respirator to be used, and additional considerations, including the need for other personal protective equipment, and heat stress.

The patient-related factors are respiratory impairment, respiratory symptoms, non-respiratory impairment (e.g., obesity, cardiac disease), psychologic factors (e.g., claustrophobia), and additional considerations, such as perforated eardrums, contact lenses, and facial hair.

The Occupational Safety and Health Administration (OSHA) regulations for respiratory protection programs require that employers provide both worker education on proper respirator usage, including selection of devices and their limitations, and a fit-testing program to ensure that the devices used will not leak. If training and/or fit-testing are not available, the evaluating physician should not clear the patient to wear a respirator.

Most evaluating physicians desire fixed criteria to clear workers for respiratory usage. The screening methods available include questionnaires, spirometry, and exercise testing.

Questionnaires can provide useful information on the presence of undue breathlessness with various types of exercise and medical or psychologic conditions that may limit ventilatory or exercise capacity. Key questions with respect to using dyspnea as a measure of respiratory impairment have already been discussed. In addition, questions should be asked regarding the presence of pulmonary or cardiac disease and other medical conditions that might limit exercise. Most physicians experienced in evaluating individuals for fitness to wear respiratory protective equipment find the use of a standardized questionnaire helpful.

Spirometry is relatively inexpensive, widely available, and provides substantial information on lung function. As a result, spirometry is the most frequently used objective test for clearance to wear respiratory protective gear. As has been reviewed elsewhere in this chapter, spirometry has limited predictive value with respect to $\dot{V}O_{2max}$. The FEV_1, however, is a good surrogate for MVV and can be used as a rough guide for determining whether exercise will be limited because of exhaustion of the ventilatory reserve.[108] An FEV_1 of 60% of predicted usually indicates that the individual has adequate ventilatory reserve for most work, including heavy labor.[53, 109] For those failing to meet this criterion, an MVV that is greater than that which would be predicted from an FEV_1 of 60% of predicted (FEV_1 at 60% of predicted × 35 to 40) would also provide good evidence of adequate ventilatory reserve.[100–102] The presence of adequate lung function by spirometry, however, does not automatically mean that the patient has adequate cardiopulmonary reserve to perform a job wearing a respirator. Factors such as intrinsic lung disease, which may raise the dead space to tidal volume ratio and ventilatory requirements for a given kind of work, or the presence of cardiac disease may result in lower than expected tolerance of exercise when a respirator is worn. Because spirometry alone is not likely to classify a high proportion of individuals as unfit to wear a respirator, clinical judgment must always be applied to the interpretation of spirometric results.

For individuals who are already performing a job, it is likely that they have the requisite cardiopulmonary fitness to do the job while wearing a respirator. For those patients who may reasonably be expected to have limited ventilatory reserve (FEV_1 or MVV < 60% of predicted) or reduced cardiopulmonary fitness in relation to the job's energy requirements, exercise testing can provide good evidence that they have adequate cardiopulmonary reserve. It should be noted, however, that if use of heavy personal protective equipment such as an SCBA is anticipated, the maximal exercise capacity should be reduced by a factor of approximately 20%.[97, 98] One practical approach to the evaluation of patients who fail to meet spirometric criteria for respirator clearance is to have them exercise while wearing the protective equipment.

Medical clearance of individuals for respirator usage remains primarily a matter of clinical judgment because there are no criteria with adequate predictive power available for the determination of who can and who cannot wear a respirator. Where a substantial question about a patient's ability to tolerate a respirator exists, spirometry can be of assistance, but observation of the patient during exercise while wearing the device may be the most practical approach.

SUMMARY

The evaluation of respiratory impairment is a multi-step process. The first step involves the determination of the degree of impairment (i.e., respiratory system dysfunction). This step is usually easier for physicians than the assessment of specific job requirements and the determination of whether the patient is physically able to perform a given job. Other steps that may be difficult for the evaluating physician are the work-relatedness of the impairment (attribution) and the percentage of the total impairment due to work-related causes (apportionment). It must be remembered that regardless of the evaluating physician's opinion(s), the final decision concerning the level of disability is made administratively by the responsible agency after consideration of non-medical factors.

The subjective complaint of dyspnea is by itself insufficient grounds to determine the level of respiratory impairment. Careful attempts to grade the degree of dyspnea with different types of activity, however, may provide important information to the evaluating physician. Spirometric parameters (FEV_1, FVC, and FEV_1/FVC) and DL_{CO} are the static pulmonary function tests that are of the most use in the evaluation of respiratory impairment. The results of these tests, for which there are well-described normative values, allow a reasonable estimate of loss of pulmonary function. If the primary question to the evaluating physician is whether the patient can perform a specific job, however, exercise testing with direct measurement of $\dot{V}O_{2max}$ may be necessary. Comparison of the patient's $\dot{V}O_{2max}$ with the energy requirements of a given job is frequently limited by insufficient knowledge of the latter.

Entitlement programs such as Social Security Disability, state workers' compensation insurance, Black Lung Benefits, etc., often require program-specific criteria for respiratory impairment determination. When specific criteria are not required, the classification scheme of the AMA or the ATS should be used. Fitness for duty evaluation may involve medical clearance to wear respiratory protective devices. Adequately validated objective criteria for such clearance that are practical for routine application are not available.

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RESPIRATORY DISEASE

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Chapter 53

RESPIRATORY IMPAIRMENT AND DISABILITY

Scott Barnhart
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Summary

The evaluation of respiratory impairment and disability seeks to address three questions: Do subjective respiratory symptoms, most commonly dyspnea, correlate with objective measures in the form of decrements in lung function? Has a patient sustained a loss of lung function at a rate greater than expected? Does the degree of impairment prevent the patient from performing the activities of daily living, including gainful employment? In addressing these questions there are a number of uncertainties, but careful attention to a rational approach can usually lead to providing the patient with a clear understanding of the cause of the dyspnea and the limits to which respiratory impairment may adversely affect his or her life.

Frequently, the evaluation of impairment and disability is done in the context of a patient being evaluated for benefits under a disability or entitlement program. These programs will provide benefits to individuals who meet program-specific criteria for the degree of impairment, and in the case of workers' compensation, criteria for attributing the cause of impairment to a workplace exposure. To aid in these evaluations, professional organizations such as the American Thoracic Society (ATS) and the American Medical Association (AMA) have developed detailed guidelines for the evaluation of impairment and disability.[1-3] A knowledge of the detailed requirements of the entitlement system, as well as any rating system required by the entitlement system, is important if a good evaluation is to take place. It is equally important to note that the physician usually does not make the determination as to whether a patient is entitled to benefits. The physician's role is usually to evaluate the patient in a standard format, to make a judgment about the presence or absence of medical diagnoses, and, in the case of workers' compensation, to assess the work-relatedness of the impairment. These results are then provided in a summary report to the administrative agency, and the administrative agency will decide whether the patient is entitled to benefits.

ETHICAL CONSIDERATIONS

The role of the physician in evaluating impairment and disability is often unique. Many patients ask their physicians for assistance in filling out workers' compensation or disability forms. In addition, many entitlement systems require the patient to consult a physician other than his or her own for an independent medical examination (IME). Evaluation of impairment and disability poses several ethical challenges that are best addressed by ensuring that the patient is well informed about the role of the physician in the process.[4]

For physicians who are treating their own patients, it is important to clearly state that their job is to acquire the data in a standard format required by the entitlement system and to review, interpret, and summarize the data objectively in offering their opinions. It is also appropriate for a patient's personal physician who has special knowledge of the unique aspects of his or her condition or care to make information available to the adjudicating agency if it is germane to the patient's level of impairment or disability. By ensuring that patients fully understand their personal physician's role, the risk of significant misunderstanding or future jeopardizing of the physician–patient relationship is minimized.

Physicians who perform IMEs are in a unique relationship with patients, which is often unprecedented in the patient's interaction with the medical system, and may be similarly new to the performing physician. The unique characteristics of an independent medical examiner are that he or she is often selected by the entitlement system rather than the patient, he or she often is not paid by the patient, he or she does not enter a physician–patient relationship, and he or she does not treat the patient beyond making recommendations to the patient's provider or to the requestor of the IME for further care and follow-up. It is extremely important that the patient understand the nature of this relationship: that the physician is required to make a fair and objective assessment. Independent medical examiners, in reviewing their status should also make clear that the results of their reports are available to the patient. This latter aspect may be problematic due to medical–legal constraints but has important ethical implications for physicians who choose to see patients and then do not make the results of their evaluation known to them.

Often, the opinions of independent medical examiners and treating physicians will be contradictory. In this situation, it is important first to recognize that the potential for bias on all sides may exist. For this reason, no single opinion should be treated as final without a very careful review of the data on all sides.

MEDICAL–LEGAL CONSIDERATIONS

The results of evaluations of impairment and disability must often be translated into a format used by an administrative agency or a legal proceeding.[5] A detailed review of the differences between the medical and legal systems is beyond the scope of this section. However, it is important to note that the standard of proof that is commonly accepted is one of "more probable than not." This is quite different from the usual standard of 95% certainty that is applied in medical research. "More probable than not" simply sets a level of proof greater than 50%.

DEFINITIONS

The vocabulary used in impairment and disability is different from that used in everyday medical terminology and often has important implications inherent to the evaluation process. Commonly used definitions include the following:

Dyspnea is the sensation of undue and/or uncomfortable shortness of breath.[6]

Impairment is the reduction of body organ function.[6]

Disability is the inability to engage in any substantial gainful activity by reason of any medically determinable mental or physical impairment or impairments.[6]

Handicap is the disadvantage for a given individual, resulting from impairment or disability, that limits or prevents fulfillment of a role that is normal (depending upon age, sex, and social and cultural factors) for that individual.[7]

Subjective refers to symptoms perceived by the patient only and not evident to the examiner.[8]

Objective refers to findings evident to the examiner in a reproducible manner and not dependent only on the patient's perceptions.

Preexisting refers to any impairment or disease that existed prior to the onset of another disease or impairment (see *Coexisting*).

Coexisting refers to any impairment or disease that exists concurrently with another disease or impairment (see *Preexisting*).

Organic impairment is an impairment explained on the basis of demonstrable abnormality, dysfunction or disease.[6]

Functional impairment is an impairment not explained on the basis of demonstrable abnormality, dysfunction or disease.[6]

Permanent partial disability is a disability at a level less than total disability that is not expected to improve.

Permanent total disability is a disability that prevents gainful employment that is not expected to improve.

Temporary disability is either total or partial disability that is thought to have a high probability of being short-term and thus can be expected to improve to a higher level of function.

CLINICAL CONSIDERATIONS

When the sensation of undue dyspnea becomes the rate-limiting factor for an individual to perform exertionally related activities, particularly gainful employment, the patient will seek medical evaluation. It is important to recognize that the patient's perception of dyspnea means much more to him or her than objective measures in either the respiratory system or other organ system. Patients care about being short of breath, not about a reduction in their forced expiratory volume in 1 second (FEV1). Entitlement systems, however, almost uniformly rely upon objective measures to base determination of disability. It is important for the physician to recognize the distinction between the subjective symptoms perceived by a patient and the objective measures required by entitlement systems, and to seek to reconcile the subjective with the objective to the greatest extent possible. When these cannot be reconciled, it is important also to recognize that the genesis of dyspnea is a complicated process incorporating both physiologic and psychologic inputs. For this reason, the inability to fully explain dyspnea on the basis of objective measures does not necessarily invalidate the symptom, even though that symptom may not meet the test required for compensation under an entitlement system.

Turning briefly to the physiologic underpinnings of dyspnea, there are several key inputs to consider in defining the clinical approach. Dyspnea can be elicited by stimulation of central chemoreceptors to arterial P_{CO_2} and, to a far lesser degree, changes in arterial P_{O_2}.[9,10] Stimulation of peripheral chemoreceptors may also result in dyspnea. Alterations in lung volume may stimulate stretch receptors, and changes in vascular pressure may stimulate C-receptor fibers. Additionally, mechanical receptors within the respiratory muscles may result in dyspnea when stimulated. The above inputs in the setting of increased minute ventilation are integrated to produce the sensation of dyspnea.

There are many disease processes within the upper and lower airways, as well as the pulmonary vasculature, that may contribute to the symptoms of dyspnea.[11,12] The measurement of dyspnea poses a substantial challenge to the clinician. It is crucial that the clinician recognize that the correlation of dyspnea with objective measures of impairment is modest.[13,14] Furthermore, mild dyspnea, which may be correlated with mild respiratory impairment, often does not represent disability with respect to the patient's current employment. For example, most white-collar jobs could be performed by patients with moderate respiratory impairment. However, jobs that require high exertion, such as performing heavy labor at a construction site, require sufficiently high cardiopulmonary capacity to not permit workers with impairment in either organ system to perform adequately.

Some reasons behind the lack of correlation between dyspnea and objective measures include the limitations in measuring dyspnea using dyspnea scales, the multiple physiologic inputs and organ systems that are integrated to cause dyspnea, the presence or absence of anxiety or other physiologic factors, and, rarely, the presence of malingering.

Dyspnea scales

The attempt to develop scales to characterize dyspnea has met with limited success.[3,11,14-18] The major utility of dyspnea scales is to provide an indication of whether the extent of dyspnea may be explained by the available objective measures. When the dyspnea cannot be sufficiently explained, it is important to proceed with further evaluation.

Dyspnea usually arises from limitations in either the respiratory or the cardiac system. Whereas acknowledging the important role of the cardiovascular system in the genesis of dyspnea, a discussion of those factors is beyond the scope of this chapter. The main pulmonary function tests used for categorizing dyspnea include spirometry, maximal voluntary ventilation (MVV), single breath diffusing capacity, and exercise capacity. None of these tests is a strong predictor of dyspnea.[13]

When assessing dyspnea scales, it is important to remember that subjective estimates of dyspnea occurring during or at the end of exertion are better correlated with measures of physiologic impairment than dyspnea recorded when the subject was at rest.[13] In addition, patient estimates of their maximal exercise capacity measured by exercise testing are relatively poor.[12,14] Similarly, neither spirometry, diffusion capacity of the lung for carbon monoxide (DLCO), nor MVV are strong predictors of oxygen consumption ($\dot{V}O_2$) max.

Malingering

Respiratory impairment has been characterized as resulting from physiologic and/or psychologic factors or, respectively, organic versus functional factors.[19] Because the evaluation of impairment and disability frequently involves potential for secondary gain, the issue of a patient malingering need always be considered. Organic impairment is defined by the presence of objective measures indicating respiratory impairment or disease. These physiologic or organic factors may include both respiratory diseases and nonrespiratory diseases, as seen with reduced oxygen delivery in the setting of cardiac failure or anemia. Where the dyspnea cannot be measured objectively, the possibility that it is based on psychologic factors must be entertained. Functional impairment is impairment that cannot be objectively measured. There are several explanations. Clearly, dyspnea is multifactorial, representing the integration of psychologic factors (e.g., anxiety) as well as physiologic factors. Objective measures are not able to fully explain all cases of dyspnea and are potentially insensitive as tests. Dyspnea may be falsely reported, as in the case of outright fraud, although in the author's experience this is quite rare. It is also possible that subconscious factors may result in amplification of dyspnea.[20]

In one important study of patients applying for compensation, it was noted that for a given level of dyspnea, those who were applying for compensation had higher levels of

FEV1.[21] These patients were also noted to have higher body masses. Although it would be incorrect to interpret that these patients applying for workers' compensation were malingering or committing fraud, medical examiners must acknowledge the potential for dyspnea to be consciously or unconsciously overestimated.

Given the inability for pulmonary function tests to fully predict dyspnea, most entitlement systems make an arbitrary decision to base ratings of impairment solely on results of objective measures.

There are several steps that may be of help when malingering is a concern. It is crucial to ensure the patient understands the goals of the evaluation so that a lack of understanding of the purpose or the performance of pulmonary function tests is not misclassified as malingering. Next, the careful review of tests to ensure that the patient has made a good effort will help assess the validity of the results. In addition, exercise testing, including a comparison of ventilatory rate, heart rate, ventilatory reserves, and work rate at maximal exercise period may aid in determining the level of effort. There is no perfect test, however, to identify malingering. Fortunately, frank malingering is rare, and a careful evaluation can usually provide the examiner with a good estimate of a patient's capabilities.

THE CLASSIFICATION OF IMPAIRMENT AND DISABILITY

The classification of impairment and disability depends upon the goal of the evaluation period. If it is simply to evaluate a patient's dyspnea and whether it may be explained by objective measures of physiologic impairment and related diagnoses, then simple scales of dyspnea and an understanding of the range of pulmonary function tests that correlate with that level of dyspnea will suffice. Often, however, the nature of the evaluation depends upon the requirements of an entitlement system. The examiner is required to meet the specifications of the entitlement system. Many entitlement programs recommend that respiratory impairment be classified according to guidelines provided by professional organizations such as the AMA, the ATS, the Canadian Medical Association (CMA), or the European Society for Clinical Respiratory Physiology.[1-3,22,23]

There are many entitlement programs, including social security disability insurance, workers' compensation, and state-based eligibility programs. Under the heading of workers' compensation, there are multiple systems, including state-based workers' compensation, federal Office of Workers' Compensation Programs, specific programs for shipyard and railway workers, and the Veteran's Administration. Under all workers' compensation systems there is a necessary requirement that impairment be attributed, usually on a "more probable than not" basis, to a workplace illness or injury.

Another program that requires impairment and disability evaluations is third-party litigation under the tort system. In addition, many individuals carry their own personal disability insurance, or employers may offer disability insurance. Finally, there may be state and municipal programs, such as eligibility for bus passes or disabled parking license plates, that depend on an impairment and disability evaluation. As is apparent from the preceding discussion, the evaluation of impairment and disability truly represents the intersection between medical evaluations and legal and administrative rules. Furthermore, the passage of the Americans with Disabilities Act (ADA) is changing the nature of what is recognized as impairment and disability and the accommodation offered to those with impairments.

Although the systems for the evaluation of impairment and disability are many, the most widely recognized and accepted system is the Guides to Evaluation of Permanent Impairment published by the AMA.[3]

The American Medical Association's Guides to Evaluation of Permanent Impairment

The AMA's *Guides to Evaluation of Permanent Impairment* represents a comprehensive system for evaluating impairment in all organ systems. Where impairment exists in more than one organ system, a method is provided to determine the percentage of total bodily impairment.

For the purpose of evaluating respiratory impairment, the guides make specific recommendations with respect to the medical history, physical examination, and laboratory tests. Under the guides, there are four classes of respiratory impairment, as shown in Table 53-1.[3] The four classes of respiratory impairment are normal, mild, moderate, and severe. Each of these impairment categories is linked to specific ranges of results from spirometry, DLCO, or $\dot{V}O_2$ max derived from exercise testing. Minimal laboratory evaluation under the guides includes spirometry and diffusing capacity. Subjective levels of dyspnea, chest radiographs, and routine arterial blood gas testing are not recommended. Resting hypoxemia with Pa_{O_2} of less than 50 mm Hg, or a Pa_{O_2} of less than 60 mm Hg along with either pulmonary hypertension or cor pulmonale, represents severe impairment.

Exercise testing is primarily reserved for those cases where subjective symptoms, such as dyspnea, are out of proportion to the objective tests. Of note, the DLCO is largely beneficial in the setting of interstitial lung disease, and corroboration with exercise testing is recommended. The ATS approaches exercise testing and maximal oxygen consumption somewhat differently.[2] Under the ATS guidelines, workers are judged able to perform their jobs comfortably when the $\dot{V}O_2$ requirements of a specific job are less than 40% of the patient's $\dot{V}O_2$ max. However, it is important to note the purpose of the disability evaluation. This "rule of thumb" is quite useful when the purpose of the im-

Table 53-1. AMA classes of respiratory impairment

Class 1: 0% no impairment of the whole person	Class 2: mild impairment of the whole person	Class 3: moderate impairment of the whole person	Class 4: severe impairment of the whole person
FVC ≥ 80% of predicted and	FVC between 60% and 79% of predicted or	FVC between 51% and 59% of predicted or	FVC ≤ 50% of predicted or
FEV1 ≥ 80% of predicted and	FEV1 between 60% and 79% of predicted or	FEV1 between 41% and 59% of predicted or	FEV1 ≤ 40% of predicted or
FEV1/FVC ≥ 70% and DLCO ≥ 70% of predicted or	FEV1/FVC between 60% and 69% or	FEV1/FVC between 41% and 59% or	FEV1/FVC ≤ 40% or
	DLCO between 60% and 79% of predicted or	DLCO between 41% and 59% of predicted or	DLCO ≤ 40% of predicted or
$\dot{V}O_2$ max > 25 ml/(kg-min)	$\dot{V}O_2$ max between 20 and 25 ml/(kg-min)	$\dot{V}O_2$ max between 15 and 20 ml/(kg-min)	$\dot{V}O_2$ max < 15 ml/(kg-min) or <1.05 L/min

DLCO, Diffusion capacity of the lung for carbon monoxide; *FEV1*, forced expiratory volume in 1 second; *FVC*, forced vital capacity; $\dot{V}O_2$, oxygen consumption.

pairment and disability evaluation is to identify whether a patient can perform a specific job. Often, however, the question posed to the examiner is whether a specific loss of function has occurred, regardless of whether the patient can perform the job. If the latter is the question to be addressed, then this "rule of thumb" of performing a job with a $\dot{V}O_2$ requirement at 40% of the patient's $\dot{V}O_2$ max is not relevant.

The ATS has made recommendations for the evaluation of impairment and disability due to asthma.[24] These recommendations provide important information and are probably more in line with modern day practice and care of patients with asthma than the more limited guidelines provided by the AMA. The ATS protocol for evaluating asthma incorporates data from three categories to determine the level of impairment among five classes. The three categories of data considered include the postbronchodilator FEV1, a measure of airway responsiveness based upon the reversibility of FEV1 following inhalation of a bronchodilator or the provocative concentration of methacholine or histamine that results in a 20% decline in FEV1, and, finally, the medication requirements when the patient is receiving optimal therapy. Each of these major categories receives a weighted score that is summed to determine the final level, as shown in Table 53-2.

The selection of the impairment level is usually performed by seeking the best fit between the levels of impairment and the results of pulmonary function tests. This does permit some freedom for the examiner, who must use good judgment in making the final determination. For example, in the setting of interstitial lung disease, it is very possible that the FEV1, forced vital capacity (FVC), and DLCO will all be reduced proportionally. In the case of diseases characterized by an obstructive defect, it is very possible to have a substantially reduced FEV1 and a normal FVC. In this setting, it would be inappropriate to look to the FVC and use that to determine the level of impairment.

Timing and use of predicted normals under the American Medical Association's Guides

Evaluations for impairment should occur when the patient is at a fixed and stable point, and not in an exacerbation of his or her illness. Protocols for spirometry and DLCO developed by the ATS set the standards for these tests. In addition, spirometry should be performed after bronchodilator.

The AMA Guides recommend using percent of predicted normal for the assessment of abnormality of the FEV1, FVC, and DLCO. The ratio of the FEV1 to the FVC is assessed as an absolute value. Predicted normal equations provided by Crapo for spirometric values and for DLCO form the basis of the AMA rating.[25,26] For the evaluation of patients who are of African or Asian descent, the Guides recommend that the predicted normal value be multiplied by 0.9. Although this recommendation is based on population-based studies, the lumping of multiple ethnicities under these broad categories as well as the issue of mixed race descent leave this area open to questions. Some examiners may prefer to use one set of predicted normals for all patients while openly acknowledging the difficulties of generalizing from predicted normals to the assessment of abnormality in a single patient.

Evaluation of specific diseases

Several disease processes are singled out for individual recommendations. Under the Guides, asthma is characterized as severe if three successive measures each spaced 1 week apart are at a level of Class Four, or severe impairment. Where sensitizers are a factor, the importance of preventing further exposure to those sensitizers is also noted. Similarly, those patients who are felt to have hypersensitivity pneumonitis are not recommended to have further exposure to the likely antigen. In the case of a pneumoconioses diagnosis, regardless of the level of impairment, further exposure to the culpable dust is not recommended. Noting

Table 53-2. ATS asthma impairment rating scheme

2a: Postbronchodilator FEV1*

FEV1 (% predicted)
>lower limit of normal
70–lower limit of normal
60-69
50-59
<50

2b: Reversibility of FEV1 or degree of airway hyperresponsiveness*

% FEV1 change	PC_{20} mg/ml
<10	>8
10-19	8->0.5
20-29	0.5->0.125
≥30	≤0.125

2c: Minimum medication needed†

Score	Medication
0	No medication
1	Occasional bronchodilator, not daily, and/or occasional cromolyn, not daily
2	Daily bronchodilator, and/or daily cromolyn, and/or daily low-dose inhaled steroid (<800 μg beclomethasone or equivalent)
3	Bronchodilator on demand and daily high-dose inhaled steroid (>800 μg beclomethsone or equivalent), or occasional course systemic steroid
4	Bronchodilator on demand, daily high-dose inhaled steroid (>1000 μg beclomethasone or equivalent), and daily systemic steroid

2d: Summary impairment rating classes (the impairment rating is calculated as the sum of the patient's scores from 2a, 2b, and 2c)

Impairment class	Total score
0	0
I	1-3
II	4-6
III	7-9
IV	10-11
V	Asthma not controlled despite maximal treatment (i.e., FEV1 remaining <50% despite use of ≥20 mg prednisone/day)

*When postbronchodilator forced expiratory volume in 1 second (FEV1) is above the lower limit of normal, PC_{20} should be determined and used for rating of impairment; when postbronchodilator FEV1 is <70% predicted, the degree of reversibility should be used; when FEV1 is between 70% predicted and the lower limit of normal, either reversibility or PC_{20} can be used.

†The need for minimum medication should be demonstrated by the treating physician (e.g., previous records of exacerbation when medications have been reduced).

the multiorgan effects of sleep apnea syndrome, the Guides recommend that impairments in each of the systems affected (e.g., nervous system, cardiovascular system, respiratory system, and mental or behavioral disorders) be assessed and combined under the formula noted in the Guide for impairment in multiple organ systems. Patients with lung cancer also receive special consideration. At the time of diagnosis, those with lung cancer are considered severely impaired. If, following treatment, at 1 year the patient is noted to be free of disease, respiratory impairment is rated based on the four classes. If the cancer recurs, the patient is again categorized as severely impaired.

Disability systems

Disability assessment is performed under several distinct administrative systems. The system employed affects the type of data collected and the manner in which they are used.

Some systems (e.g., the U.S. Social Security Disability Insurance System) do not require determination of causation of the respiratory disease; assessment is made only of its physiologic impact. Conversely, most workers' compensation systems in the United States require explicit assessment of the specific medical diagnosis and also of the degree to which it is work related.

When causation is an issue to be resolved, some systems allow disability compensation only if the putative causative agent is on a prescribed list, whereas others consider each case individually. To a large degree, British systems depend upon scheduled lists, whereas American systems tend to be less structured. Furthermore, certain respiratory disability assessment systems are limited to diseases due to a specific agent (e.g., coal-related disease).

Some systems seek to determine the presence or absence of only complete and total impairment, whereas others mandate considering the full range of impairment. Generally, workers' compensation requires rating of the degree of partial disability.

The flexibility of assessment varies among systems. Some are nearly completely prescriptive, describing in detail which tests are to be performed as well as the criteria for their interpretation. For example, under Social Security, the patient's test results are compared with specific criteria values in tables. Other systems, such as tort evaluations in the United States, have no preset criteria. In such circumstances, there may be conflicts of opinion about the significance of minor deviations from average values for parameters such as midexpiratory flow rates. In some settings, scheduled awards are made, in which the amount of compensation is determined from tables based solely on lung function tests, whereas in other situations, physician or patient opinion very much influences the degree of compensation.

To facilitate processing, some systems employ presumptions. These are rules that define work relatedness on administrative rather than medical basis. For example, in the United States, lung function abnormalities in individuals in the coal industry covered by the Black Lung laws are automatically presumed to be work related. Such presumptions are occasionally rebuttable if one or another side of a case can demonstrate that the presumption is inaccurate.

Systems differ administratively. Pneumoconiosis Medical Panels may be employed, in which a predesignated panel of expert physicians (occasionally government employees) examines each case and jointly reaches conclusions about causation and degree of disability. Such methods are rarely used in the United States, in which individual physicians evaluate cases. This leads to more controversy. The efficiency and consistency of the Panel approach have led many to favor it. In addition, these also (theoretically) ensure that the examiner has the necessary expertise. However, evaluation by individual physicians is felt by many to be essential to ensure fairness to both workers and their employers. The possibility of undue political influence on Panels raises concerns; in addition, Panels may become fixed in thought patterns and slow to adapt new information. Many in the United States quote the Black Lung regulations as an example of a compensation system in which political motives have superseded scientific considerations. Hybrid systems also exist, in which government evaluators (occasionally physicians) review records and may request an examination by an independent physician if needed; the U.S. Railroad Retirement Board illustrates this method.

In summary, there are very significant differences in how respiratory disability assessments are conducted. These range from rigid government-based systems in which a small number of designated "experts" evaluate each case using predesignated criteria for disease due to agents on a specific list to highly adversarial systems with few if any agreed-upon criteria.

Specific entitlement systems: Social Security disability insurance

The Social Security Disability Insurance Program and the Supplemental Security Income (SSI) program are both administered by the Federal Social Security Administration.[27] The Social Security Disability Insurance Program provides disability benefits to patients who have made regular contributions to Social Security. In addition, to prevent disabled persons from becoming destitute, the Social Security Supplemental Income Program provides benefits to persons who have severe impairment and meet specific criteria with respect to fiscal assets. Eligibility for either program is based upon the presence of severe impairment for a period of at least 1 year.

Social Security provides specific criteria for three broad categories of respiratory impairment. These are chronic obstructive pulmonary disease, chronic restrictive ventilatory disorders, and chronic impairment of gas exchange. As shown in Tables 53-3, 53-4, and 53-5, the criteria for eligibility for each category are quite strict. Moreover, the lack of adjustment for age or sex biases these criteria against males and those of younger age groups. Another specific disorder considered under Social Security is asthma. Criteria for severe asthma impairment may be met either under the criteria for obstructive disorders or by noting the presence of severe asthmatic attacks an average of six times per year with wheezing present in the interval periods. This strict criterion should be reviewed against the graduated spectrum of impairment provided under the more recently defined ATS guidelines, which require that the patient receive optimal therapy and consider several parameters in determining impairment. It should be noted that there are few asthmatics who, when optimally treated, would meet the SSI criteria, and those who do likely deserve a second opinion to determine whether medical therapy is optimal. Patients with pneumoconiosis, bronchiectasis, or mycobacterial disease also receive special consideration but generally should be reviewed under the criteria for restrictive or obstructive diseases.

There are specific criteria provided for evaluating patients with cor pulmonale. Finally, many patients have multiple diseases contributing to their total impairment, and these should all be considered in the report documenting

Table 53-3. Social Security disability rating scheme for COPD

Height without shoes (inches)	FEV1 equal to or less than	MVV equal to or less than (L/min)
60 or less	1.0	40
61-63	1.1	44
64-65	1.2	48
66-67	1.3	52
68-69	1.4	56
70-71	1.5	60
72 or more	1.6	64

COPD, Chronic obstructive pulmonary disease; *FEV1*, forced expiratory volume in 1 second; *MMV*, maximal voluntary ventilation.

Table 53-4. Social Security disability rating scheme for restrictive disorders

Height without shoes (inches)	VC equal to or less than
60 or less	1.2
61-63	1.3
64-65	1.4
66-67	1.5
68-69	1.6
70-71	1.7
72 or more	1.8

VC, Vital capacity.

Table 53-5. Social Security disability rating schemes for disorders of gas exchange*†

Arterial Pco_2 (mm Hg) and	Arterial Po_2 equal to or less than (mm Hg)
Applicable at test sites less than 3,000 feet above sea level	
37	58
38	57
39	56
40 or above	55
Applicable at test sites 3,000 to 5,000 feet above sea level	
37	53
38	52
39	51
40 or above	50
Applicable at test sites over 6,000 feet above sea level	
30 or below	55
31	54
32	53
33	52
34	51
35	50
36	49
37	48
38	47
39	46
40 or above	45

*Steady-state exercise blood gases demonstrating values of Pao_2 and simultaneously determined $Paco_2$, measured at a workload of approximately 17 ml O_2/kg/min or less of exercise, equal to or less than the values specified in the table.

†Diffusing capacity for the lungs for carbon monoxide less than 6 ml/mm Hg/min (steady-state methods) or less than 9 ml/mm Hg/min (single breath method) or less than 30% of predicted normal. All methods, actual values, and predicted normal values for the methods used should be reported.

impairment. Providers and patients should also be aware that an initial rejection of a claim for benefits under Social Security leaves open the door for an appeal, which may substantially increase the patient's chance of receiving benefits.[28,29]

Workers' compensation

Workers' compensation covers a broad range of, but not all, occupations. Central to workers' compensation is attributing a disease and impairment related to that disease on a "more probable than not" basis to an occupational exposure.[5,30] Understanding the broad range of workers' compensation systems and multiple different requirements under each system for both the provider and the patient can be likened to obtaining health benefits in the current era of health care reform—too many requirements with too little coverage. There are separate workers' compensation systems in each state; within states not all workers may be covered, and there may be state insurance funds, self insurance by large companies, and third party insurance provided by large insurance companies. Shipyard workers, railway workers, federal workers, veterans, and seafarers all operate under different systems. It is essential that the patient and provider determine under which system a claim for benefits may be filed and also the specific requirements of the system. It is also important to note that railway workers and merchant mariners are covered under liability acts where the worker must obtain the services of an attorney to file a claim.

As mentioned earlier, the key criterion for receiving benefits is attribution of the illness and impairment on a "more probable than not" basis to a workplace exposure. Given limitations in the current knowledge of occupational illnesses, the multifactorial nature of disease causation and the frequent long latency between exposure and disease, attribution is a difficult task that often requires balancing a number of uncertainties. For this reason claims for occupational illnesses are frequently contested.[28] It is also important for physicians to note their role in workers' compensation claims. Physicians are obligated to diagnose and treat work-related illness, and when attributing illness to an occupational exposure, to inform the patient, and to assist with the appropriate documentation to file claims for benefits. The awarding of benefits, however, is an administrative matter that is out of the control of the physician. An especially important point to be aware of is that the physician must be clear of the level of certainty at which an attribution to workplace exposure is made. As noted above, the test is on a "more probable than not" basis; thus, indicating that a disease is possibly related (less than 50% probability) will, in most situations, result in no benefit being awarded. On the other hand, a level of certainty higher than "more probable than not" (e.g., 95% certainty) is not required. Often, physicians are faced with situations where further exposure may result in immediate or long-term harm to the patient. For example, patients with occupational asthma who continue to be reexposed may have an immediate risk due to a severe asthmatic reaction, or may also risk greater long-term impairment as a result of their continued exposure. In this situation physicians may need to discuss in detail with the patients early removal from work and placement on temporary total disability. Ideally, one would have a workers' compensation system that would adjudicate such matters and approve benefits, including the time loss for temporary total disability, without delay. Many workers' compensation cases, however, drag on for weeks, months, and sometimes years, and thus the physician and patient often need to make a decision about removal from work on the best available evidence prior to adjudication of the claim. Given these real life situations, it is important for the physician to explain the process carefully to the patient, including who determines the awarding of benefits, as well as the medical facts for consideration and the extent to which the physician is able to support the claim. A physician should be extremely careful about removing a patient from work, especially if he or she is not willing to strongly support the patient for benefits under workers' compensation. To do less is potentially to jeopardize the patient's livelihood.

Department of Veterans Affairs

The Veterans Administration provides disability to those veterans who have service-connected injuries or illnesses. Under the Veterans Administration there is a highly codified rating system for impairment where specific diseases are rated on a 0% to 100% basis.[31] Ratings are based on both clinical symptoms and objective measures of lung function. However, because specific levels of pulmonary function are not tied directly to levels of impairment, there is ample opportunity for the evaluating physician to interpret the results. Provided in Table 53-6 are rating schedules for common respiratory diseases.

Black Lung Benefits Act

The Black Lung Act is designed to provide benefits for disability among coal miners. The basic evaluation includes chest roentgenograms, physical examination, and pulmonary function tests (including arterial blood gas measurement).[32] Chest radiographs are classified under the International Labor Office system.[33] There are also alternative methods under which one may become eligible. These include histologic evidence of pneumoconiosis, or, in the face a negative chest radiograph, a finding by a physician that the miner suffers impairment attributable to a pneumoconiosis. Miners may be eligible by presumption if they have been employed for a minimum of 15 years and have a totally disabling respiratory impairment, regardless of cause.

Benefits are provided to eligible miners or dependents who are considered totally disabled. Those who cannot perform usual coal mine work or other gainful employment available in their immediate area of residence are considered totally disabled.[32] Specific criteria for pulmonary function tests are also included based on the regression equations of Knudsen et al.[34] When compared with the reference values used by the ATS and the AMA, total disability is defined as an FEV1 of approximately 58% of predicted.[2,3,25] It should be emphasized that there is opportunity for physicians to provide input.

CLINICAL APPROACH TO THE EVALUATION OF RESPIRATORY IMPAIRMENT

The approach to evaluating patients for respiratory impairment follows the standard medical history and physical and laboratory evaluation. There are, however, several caveats. As noted, the specific requirements of the system under which benefits may be sought should be reviewed and addressed. Where workers' compensation may be a consideration, attribution to a workplace exposure becomes an important point in the evaluation. Finally, the approach should seek to explain fully the physiologic underpinnings of dyspnea and resort to attributing dyspnea to functional factors as a last resort.

Medical history

The medical history should be a comprehensive history with additional specific attention to respiratory symptoms, including dyspnea, cough, production of phlegm, chest tightness, and wheezing. The usual characterization of intensity, onset, duration, and progression should be noted. It may be beneficial to try to categorize the extent of dyspnea according to either the questions of the ATS Epidemiology Standardization Project[17] or those provided by the AMA (see Table 53-7).

The medical history should also assess symptoms related to the cardiovascular system in detail and include the usual review of systems and past medical history.

The occupational history should focus on a detailed description of the current job, including exposures and use of personal protective equipment. Where there are questions regarding the exposures, the patient should be asked to bring in material safety data sheets (MSDS) for each exposure. The use of personal protective equipment, the availability of facilities for personal hygiene, and a separate area to eat meals should also be ascertained. A detailed listing of all prior jobs should also be made.

The work history should review whether there is a temporal association between symptoms and exposures. The examiner should keep in mind that important points for attributing a disease to a workplace exposure include the following steps: (1) obtaining a diagnosis, (2) identifying a potential exposure that could be a plausible cause of the disease, (3) excluding other potential causes of the disease, and (4) identifying whether there is an appropriate temporal relationship between the exposure and disease, as well as an appropriate dose and duration of the exposure.

Avocational activities should be reviewed in the history. Some patients may have hobbies that expose them to high levels of fumes, dust, or chemicals. A detailed smoking history should be obtained. Additionally, a review of other habits, including ethanol usage and inhaled substance abuse, should be made. The patient and the physician should keep in mind that the medical record may not be kept fully confidential in workers' compensation cases and other medical legal matters, and it may become available to the insurance company, employer, or other party. For this reason, while it is important that appropriate pertinent medical information be part of the file, the inclusion of material not relevent to the evaluation should be approached with the limits of confidentiality under workers' compensation in mind.

Physical examination

Physical examinations should include a thorough physical examination with a strong emphasis on the respiratory and cardiovascular systems. The pertinent positives and negatives should be included in the report.

Table 53-6. Veterans Administration rating schedule for chronic obstructive pulmonary disease, asthma, and pneumoconiosis

	Rating
Chronic bronchitis	
Pronounced—With copious productive cough and dyspnea at rest; pulmonary function testing showing a severe degree of chronic airway obstruction; with symptoms of associated severe emphysema or cyanosis and findings of right-sided heart involvement	100
Severe—With severe productive cough and dyspnea on slight exertion and pulmonary function tests indicative of severe ventilatory impairment	60
Moderately severe—Persistent cough at intervals throughout the day, considerable expectoration, considerable dyspnea on exercise, rales throughout the chest, beginning chronic airway obstruction	30
Moderate—Considerable night or morning cough, slight dyspnea on exercise, scattered bilateral rales	10
Mild—Slight cough, no dyspnea, few rales	0
Bronchiectasis	
Pronounced—Symptoms in aggravated form, marked emphysema, dyspnea at rest or on slight exertion, cyanosis, marked loss of weight or other evidence of severe impairment of general health	100
Severe—With considerable emphysema, impairment in general health manifested by loss of weight, anemia, or occasional pulmonary hemorrhages; occasional exacerbations of a few days duration, with fever, are to be expected; demonstrated by lipoidol injection and layer sputum test	60
Moderate—Persistent paroxysmal cough at intervals throughout the day, abundant purulent and fetid expectoration, slight, if any, emphysema or loss of weight	30
Asthma	
Pronounced—Asthmatic attacks very frequently with severe dyspnea on slight exertion between attacks and with marked loss of weight or other evidence of severe impairment of health	100
Severe—Frequent attacks of asthma (one or more attacks weekly), marked dyspnea on exertion between attacks with only temporary relief by medication; more than light manual labor precluded	60
Moderate—Asthmatic attacks rather frequent (separated by only 10-14 day intervals) with moderate dyspnea on exertion between attacks	30
Mild—Paroxysms of asthmatic type breathing (high pitched expiratory wheezing and dyspnea) occurring several times a year with no clinical findings between attacks	10
NOTE: In the absence of clinical findings at time of examination, a verified history of asthmatic attacks must be of record.	
Emphysema	
Pronounced—Intractable and totally incapacitating; with dyspnea at rest, or marked dyspnea and cyanosis on mild exertion; severity of emphysema confirmed by chest x-rays and pulmonary function tests	100
Severe—Exertional dyspnea sufficient to prevent climbing one flight of steps or walking one block without stopping; ventilatory impairment of severe degree confirmed by pulmonary function tests with marked impairment of health	60
Moderate—With moderate dyspnea occurring after climbing one flight of steps or walking more than one block on level surface; pulmonary function tests consistent with findings of moderate emphysema	30
Mild—With evidence of ventilatory impairment on pulmonary function tests and/or defined dyspnea on prolonged exertion	10
Pneumoconiosis	
Pronounced—With extent of lesions comparable with far advanced pulmonary tuberculosis or pulmonary function tests confirming a markedly severe degree of ventilatory deficit; with dyspnea at rest and other evidence of severe impairment of bodily vigor producing total incapacity	100
Severe—Extensive fibrosis, severe dyspnea on slight exertion with corresponding ventilatory deficit confirmed by pulmonary function tests with marked impairment of health	60
Moderate—With considerable pulmonary fibrosis and moderate dyspnea on slight exertion, confirmed by pulmonary function tests	30
Definitely symptomatic with pulmonary fibrosis and moderate dyspnea on extended exertion	10

Table 53-7. AMA classification of dyspnea

Mild	Dyspnea is present with fast walking on level ground or walking up a slight hill; the person can keep pace with other persons of same age and body build on level ground but not on hills or stairs
Moderate	Dyspnea is present while walking on level ground with persons of the same age and body build or walking up one flight of stairs
Severe	Dyspnea is present after the person walks more than 4 to 5 minutes at own pace on level ground; the person may be short of breath with less exertion, or even at rest

Laboratory tests

Chest radiographs are of limited use in assessing impairment. They are, however, an important component in assessing the presence of pulmonary, as well as extrapulmonary, disease. In the vast majority of cases, a chest radiograph should be obtained. Where pneumoconiosis is suspected, the film should be read by a physician trained in the classification of pneumoconioses according to the system of the International Labor Office.[33]

Pulmonary function tests

Spirometry forms the cornerstone of the impairment evaluation based on pulmonary function tests. Lung volumes, arterial blood gas, single breath diffusion capacity, and exercise play important roles as well. Spirometry and diffusing capacity measurements should be performed according to the ATS recommended standards.[35-37] One should note, however, that there are limitations in the predictive value of spirometry and the other tests, including DLCO, in predicting exercise capacity as measured by $\dot{V}O_2$ max.[38-41] Of measurements of lung volume, FVC provides the best measure in conjunction with FEV1. Of additional importance is the use of predictive equations. The ATS and the AMA recommend the use of predictive equations by Crapo and colleagues.[25,26] Of note, however, the Black Lung Act is based on the use of regression equations by Knudsen et al.[34] Although the use of specific predictive equations may or may not be required by a particular entitlement system, it is important for the examiner to recognize that there are some relatively small variations among predictive equations when used for spirometry and that they are much larger with DLCO.[42]

As noted above, the AMA also recommends a correction factor for patients of African or Asian descent. The correction factor involves multiplying the predicted value for Caucasians by 0.9.[3] Although there is substantial documentation in the literature for the occurrence of ethnic variations and variations based on gender, the use of correction factors should be approached with caution. It should be recognized that the aggregation of all Africans and all Asians into a single ethnic group and the issue of mixed racial descent limit the generalizability of this adjustment.

Finally, the single breath diffusion capacity frequently has marked intralaboratory variability. For this reason it is recommended that careful attention be directed at test performance according to the ATS criteria.[36] In reporting results, the ATS recommends that laboratories use the regression equations of Crapo and Morris.[26] These results should be adjusted to a standard hemoglobin ratio of 12.8 g/dl for women, and 14.6 g/dl for men. When corrected for severe anemia or erythrocytosis, uncorrected values should be reported as well. In addition to respiratory diseases, other factors may affect the DLCO, including hemoglobin concentration and altitude. Most important, however, is the performance of the test, which requires inspiration of 90% of the vital capacity and a standardized breathholding time. Of these two factors, diminished inspiratory volume is by far the most important.

Arterial blood gas measurement

There is relatively poor correlation between resting arterial PaO_2 and exercise capacity. The ATS statement recommends that the PaO_2 be considered only in cases that straddle two classes of impairment.[2] Because arterial hypoxemia shows great variability, it is recommended that at least two measurements at least 4 weeks apart be obtained.

Exercise testing

When the purpose of loss of function is the goal of the evaluation, there is frequently little need for exercise testing. On the other hand, when the goal is to determine whether a patient can perform a job with a known energy requirement, then exercise testing has great utility if the answer is not obvious from spirometry and DLCO, or from the patient's history. However, there are limitations to directly tying maximal oxygen consumption with work.[43] For example, if the patient describes an active occupational and avocational lifestyle, has no respiratory complaints, and has normal spirometry and DLCO, there is likely little to be gained by exercise testing. On the other hand, patients may have modest impairments in spirometry or DLCO and still be capable of performing a wide variety of jobs with substantial energy requirements. For these latter patients, exercise testing provides a valuable tool to overcome the recognized limitations in spirometry and DLCO in predicting exercise tolerance.[39,40,44] Along these lines, the ATS recommends using exercise testing in those situations where the static pulmonary function tests, such as spirometry and DLCO, may underestimate the level of the patient's impairment.[2] In summary, exercise testing is useful to determine a worker's exercise capacity, but it is not useful in situations where the goal is to determine objectively the loss of function, in situations where the patient clearly has a severe respiratory impairment, or in those instances where history, physical examination, and static lung function test demonstrate normal respiratory function.[40]

An advantage of exercise testing is that it does give, in a standardized fashion, a measure of oxygen consumption that may be related to a patient's job. Additionally, patients may be directly observed, and there are several parameters to examine that may indicate both the extent of patient effort and other causes of dyspnea. In particular, examination of the work rate, $\dot{V}O_2$ max, heart rate, oxygen pulse, anaerobic threshold, and V_d/V_t all are of use. Direct measurements of arterial blood gas, oxygen concentration in mixed expired gas, and total minute ventilation are preferred over extrapolations from work rate, heart rate, and submaximal test results.

There has been considerable controversy over whether exercise tests should be maximal, symptom limited tests or submaximal tests.[1,2,40,44,45] While substantial information may be derived from submaximal tests, determination of maximal work capacity is by extrapolation. This may result in underestimation of $\dot{V}O_2$ max.[45] Given the controversy, it is reasonable to follow the ATS recommendation for maximal exercise tests.[2]

Whether $\dot{V}O_2$ max has been estimated or directly measured, the value may be used to determine the patient's ability to perform a job based on the energy requirements for that work.[46-50] Exercise physiologists generally feel that a patient can work for an 8-hour shift at a level of energy expenditure that is 40% of his or her $\dot{V}O_2$ max. In general, a patient whose $\dot{V}O_2$ max is 25 ml/kg/min or greater is capable of performing all but the most physically demanding jobs. Between 15 and 25 ml/kg/min, the energy requirements of the specific jobs should be estimated. Where the patient's $\dot{V}O_2$ max is less than 15 ml/kg/min, he or she is considered generally unable to perform most jobs. Table 53-8 provides a rough guide for energy requirements for some jobs.

A critical limitation in the application of exercise testing to estimate a patient's capacity to perform a job is the lack of specific information about job demands or energy requirements.[46-50] For this reason, examiners should pay particular attention to characterizing the work requirements of current jobs. Further research is definitely needed in this area.[51] Methods of assessing job demands are discussed in Chapter 52.

Table 53-8. Energy requirements of various types of work

	$\dot{V}O_2$ (approximate)		
	ml/kg/min	**L/min**	**METS**
Light to moderate work (sitting)			
Clerical	5.6	0.42	1.6
Using repair tools	6.3	0.47	1.8
Operating heavy equipment	8.8	0.66	2.5
Heavy truck driving	12.6	0.95	3.6
Moderate work (standing)			
Light work, own pace	8.8	0.66	2.5
Janitorial work	10.5	0.79	3.0
Assembly line (lifts 45 lb+)	12.3	0.92	3.5
Paper hanging	14.0	1.05	4.0
Standing and/or walking (arm work)			
General heavy labor	15.8	1.19	4.5
Using heavy tools	21.0	1.58	6.0
Lift and carry 60-80 lb	26.2	1.97	7.5

METS, 3.5 ml O_2/kg/min; *$\dot{V}O_2$*, oxygen consumption.

EVALUATION OF SPECIFIC RESPIRATORY IMPAIRMENTS

Chronic airflow obstruction

There are several considerations for evaluating patients with chronic airflow obstruction. As mentioned earlier, spirometry, in particular FEV1, shows a fairly high correlation with exercise limitation.[14,52,53] Whereas on a population basis there is a high correlation between spirometry and $\dot{V}O_2$ max, prediction of exercise tolerance for an individual worker using spirometry is relatively limited. Patients with chronic bronchitis who may have only modest decrements in their FEV1 and relatively modest impairment with respect to $\dot{V}O_2$ max may, due to their heavy production of sputum, be unable to wear a respirator. In addition, concomitant disorders such as cor pulmonale may compound the degree of impairment.

Asthma

As noted previously, ATS has provided recent recommendations on the evaluation of asthma. As with chronic airflow obstruction, individuals with asthma, regardless of cost, are subject to aggravation when exposed to inhaled irritants such as dust fumes, gases, or smoke. For this reason, asthma should be evaluated not only with respect to impairment, but also when establishing whether a patient can return to work. The absence of triggers should be assessed.[24] For patients whose asthma is caused by a specific sensitizer as with exposure to isocyanates, the relative contraindication of exposure to inhaled irritants becomes much more of an absolute contraindication. In addition, it is important for those identified with asthma induced by a sensitizer to be removed fairly quickly after exposure, as this will lessen the likelihood of long-term impairment disability.[54] In addition, a patient's failure to improve dramatically after cessation of exposure is by no means an argument that the asthma was not caused by the potential offending agent.[55]

The ATS statement places patients with asthma induced by sensitizers in a unique category and considers them totally impaired for any job involving exposure to the causative agent.[2,3] In addition, attention should be directed to whether the impairment or disability is permanent or temporary.[24] In those cases where the asthma is recently diagnosed or treatment is considered inadequate, the asthma should be rated as temporary. In these situations a temporary rating should be given and specific recommendations provided to the treating physician. Evaluation should occur in 6 months or whenever the treatment objectives are obtained. When the asthma appears to be stable, symptoms appear to be minimal, pulmonary function is at a maximum on the least extent of medications to achieve this control, and no further improvement is likely, then a permanent rating should be performed.

Interstitial lung disease

In a landmark study by Epler and co-workers, DLCO and resting spirometry were good predictors of the extent of dyspnea.[13] Histologic severity of disease did not correlate well with resting lung function. With occupationally induced interstitial lung diseases, the diagnosis of pneumoconiosis in the setting of normal respiratory function may still represent an impairment in that the patient should no longer be exposed to that dust. An absolute contraindication to exposure as with occupational asthma due to sensitizers, however, does not exist. With the appropriate use of personal protective equipment and adequate administrative and engineering controls, individuals with pneumoconiosis can work provided that further exposure, except at the most minimal level, does not continue.[2,3] Hypersensitivity pneumonitis, however, should be viewed in a fashion similar to occupational asthma and further exposure cannot be recommended.[2] The evaluator must recognize, however, that for some workers, this is not possible. For example, farmers who develop hypersensitivity pneumonitis may be encouraged to prevent further exposure by giving up their farm. For obvious reasons, many are reluctant to comply. In these less optimal situations, an emphasis on ventilation, avoidance, and use of personal protective equipment may provide a middle ground as long as all parties recognize the risks.

Sleep apnea

Sleep apnea is associated with impairment in two ways. The first is the presence of hypoxemia resulting in cor pulmonale, which when present represents a severe impairment. The second is that day time hypersomnolence may result in sufficient inattention to make working in certain jobs, such as driving, contraindicated.[2] Similarly, if the patient has a history of cough resulting in syncope, this too represents an impairment.[2] Finally, patients with severe bullae or airflow obstruction are not recommended to work as divers. In addition, if high altitude flying in unpressurized cabins is a concern, the risks of barotrauma should also be taken into consideration.

CLINICAL ASSESSMENT OF IMPAIRMENT AND DISABILITY AND REQUIREMENTS FOR REPORTS

In general, most evaluations require a comprehensive report. This need not be overly burdensome but should include the pertinent positives and negatives on history, physical examinations, and laboratory tests. Certain entitlement systems will also require that the actual pulmonary function test results, including tracings of spirometry, be included.

The discussion section should begin with a very brief summary of the problem or question being addressed, the diagnosis, and the degree of impairment. For workers' compensation claims, it is important that there be a discussion on attribution. Attribution is a process whereby a disease is caused or aggravated by a workplace exposure.[28] Attribution is generally done on a "more probable than not," or 51% probability, basis. Frequently, examiners will have to rely upon the detailed occupational history and generalize to the epidemiologic literature, as well as to literature on mechanisms, to decide whether a disease may be attributed to a workplace exposure. This is especially challenging where there is multifactorial causation. It is important to recognize that many factors may be additive or synergistic. Important considerations for attribution include the extent or certainty with which the diagnosis is established: Is it plausible that the diagnosed disease was caused by the exposure? Was the intensity and duration of the exposure sufficient to cause or aggravate the disorder? Finally, was there an appropriate temporal association? This latter point should take into consideration that some diseases, such as an acute inhalation injury, should have a very close temporal relationship, whereas others, such as asbestosis, may have 20 or more years latency between first exposure and the development of the disease.

Many workers' compensation systems will ask the examiner also to address the challenging issue of apportionment.[56] Apportionment is used to assess the relative contributions of multiple factors in the genesis of a disease or impairment. Although it is theoretically possible to apportion among cases when excellent data on expected contributions are available and when these contributions are additive, for the most part, the interaction of multiple factors in causing disease, whether additive or synergistic, and the difficulties of exposure assessment make apportionment extremely problematic. For this reason, apportionment should be approached with great caution. When examiners must apportion, they should do so recognizing the pitfalls that may occur due to uncertainties of exposure assessment or failure to recognize that the synergistic interaction of factors is much more important than the contribution of either single factor alone. For example, among asbestos insulators the risk of cigarette smoking has been noted to increase the risk of lung cancer tenfold. Asbestos exposure was shown in this group to increase the risk of lung cancer fivefold. When both factors were present together, the risk of lung cancer increased fiftyfold. Clearly, the synergistic interaction of asbestos and cigarette smoking is the most powerful risk factor. In this setting it is obvious that apportionment based on relative contributions is not possible because taking cigarettes away would eliminate 90% of the cancers, and taking asbestos away would eliminate 80% of the cancers. In summary, while apportionment may well be a fact of life, it should be approached with great caution, and one should remember that the apportionment is more often precise than accurate.

SUMMARY

The evaluation of impairment and disability represents the intersection between medicine and the administrative and legal system. Although much of what needs to be done requires following a cookbook approach to meet the specific requirements of an entitlement system, there are also substantial challenges to the medical practitioner. The medical practitioner must use careful judgment in making a diagnosis and obtaining the appropriate laboratory tests to characterize the extent of impairment, as well as the presence and contribution of other nonrespiratory diagnoses. Many of the entitlement systems rely heavily upon the judgment and input from the evaluators, and care must be taken to provide the most unbiased account possible. The process also requires substantial skill in working with patients, a process that works best when the patient is well informed of the purpose of the evaluation and has an opportunity at the close to have full access to his or her report.

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debate in print

Asbestos-Related Disorders*

A Realistic Perspective

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(CHEST 1997; 111:1424-26)

Millions of workers have had occupational exposure to asbestos throughout the last century. While the literature is replete with descriptions of asbestos-related disorders, it is difficult to accurately determine current prevalence and incidence rate of asbestosis. There are several reasons for this

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difficulty. First, since asbestosis is a dose-related disease and workplace asbestos exposures have decreased over the last several decades, past occurrence data for asbestosis do not apply to present cohorts.[1] Second, the clinical diagnosis of asbestosis encompasses criteria of variable specificity.[2] Therefore, the frequency of diagnosing asbestosis varies inversely with the degree of specificity applicable to the criteria utilized. Without utilizing uniform criteria, occurrence data between different studies are not comparable.

Although various approaches to diagnosing asbestosis have been outlined,[3] three criteria should be emphasized.[4] First, asbestos exposure of significant intensity, duration, and latency must have occurred. A simple dichotomous response of "yes" to the question "have you been exposed to asbestos?" is insufficient in fulfilling this criterion. To assess whether significant exposure has taken place, a thorough understanding of the specifics of an individual's occupation is mandatory. This understanding encompasses determining the direct or indirect nature of the asbestos exposure, whether the work site was open or enclosed, what (if any) protective equipment was worn, etc.

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Next, it is imperative to confirm that fibrosis exists. When the interstitial changes on chest radiograph are considered minimal or even absent, how is documentation of fibrosis made? It has been demonstrated that high-resolution CT (HRCT) is a sensitive tool for this purpose.[5,6] However, the linear and irregular parenchymal opacities present on HRCT in association with interstitial fibrosis lack specificity for diagnosing asbestosis.[7] A multitude of other diseases and conditions similarly affect the lung parenchyma, producing these abnormalities. Thus, while documenting the presence of fibrosis is essential, and HRCT is useful in this respect, the predictive value of these findings alone is low for establishing the existence of asbestosis. Obviously, their predictability increases when they occur in association with asbestos-related bilateral pleural plaques.

It follows from this discussion that a third criterion must be met when considering the diagnosis of asbestosis, namely the exclusion of confounders for the presence of pulmonary fibrosis. This criterion was outlined in the American Thoracic Society statement,[2] emphasized by Jones,[4] and shown to be important by Gaensler.[8] Gaensler investigated a population in which the diagnosis of asbestosis had been made on clinical grounds, but was not subsequently established pathologically. Rather, idiopathic pulmonary fibrosis, bronchiolitis obliterans, and other conditions accounted for the presence of fibrosis. As Gaensler pointed out, while the prevalence for nonasbestos-induced interstitial lung disease in this select study population was low (5.1%), the future occurrence of such cases will be increasing because asbestosis is a disappearing disease. It should be noted that among these individuals with nonasbestos-induced interstitial lung disease, when compared to matched controls, their work histories were consistent with indirect asbestos exposure of lower intensity.[3]

Thus, before establishing the diagnosis of asbestosis, asbestos exposure must have been deemed significant, the presence of fibrosis documented, and the absence of confounding factors confirmed. Fulfilling these criteria is also critically important when attempting to attribute asbestos exposure as a causative factor for the development of lung cancer. Failure to fully consider the presence or absence of these criteria has inadvertently led to the conclusion that past asbestos exposure is etiologically related to lung cancer even when chest radiograph documentation of asbestosis is absent.[9]

When the criteria for establishing the clinical diagnosis of asbestosis are considered "soft," more reliance should be placed on confirming the presence of this pneumoconiosis pathologically. Lung biopsies, including newer thoracoscopic techniques for the purpose of diagnosing interstitial lung disease, can be performed with minimal morbidity and mortality.[10-12] The pathologic criterion of finding more than one asbestos body in areas of fibrosis will establish the diagnosis of asbestosis.[13] Alternatively, other specific causes for the interstitial process can be determined and potential therapy given. While the quantitative analysis of lung tissue and bronchoalveolar lavage for asbestos fibers and bodies can verify the occurrence of significant past asbestos exposure, the variability of data generated between laboratories on the same specimen,[14] coupled with the limited number of qualified facilities able to perform the analyses, significantly narrows the clinical usefulness of this methodology in contributing to the diagnosis of asbestosis. At the present time, fiber burden analysis remains a useful research tool for studying asbestos-related disorders. This also applies to analyzing bronchoalveolar fluid for inflammatory mediators and cellularity.[15,16] The histologic examination of lung tissue remains the gold standard for confirming the existence of asbestosis.

Since most asbestos exposure is occupationally related, once an asbestos-related disease is diagnosed, a personal injury claim frequently follows. The specificity of the criteria utilized in establishing the presence of asbestos-related diseases directly influences the number of personal injury claims made. Before 1995, 120,000 asbestos-related claims were disposed of, either through the judiciary process or through negotiation.[17] It has been estimated that there are 135,000 pending asbestos-related law suits,[18] with estimates that up to 250,000 new claims will be made in the future.[17] Also, the specificity utilized in diagnosis probably has a direct bearing on estimates for asbestos-related cancer deaths. It has been projected that for the period 1985 to 2009, this figure will approach 131,200.[19]

The magnitude of asbestos-related personal injury claims (past, present, and future) and projected cancer deaths is staggering. However, quantifying risk for developing these disorders can also be done with actual asbestos-related mortality data. The 1994 *Work-Related Lung Disease Surveillance Report* published by the National Institute for Occupational Safety and Health (NIOSH) has determined that between 1968 and 1990, the total number of deaths associated with asbestosis in the United States was 8,215.[20] These data can be utilized to gauge a more realistic projection for the occurrence of asbestosis. It has been determined that approximately 20% of individuals certified as having asbestosis die of their pneumoconiosis.[21] With this understanding, the 8,215 asbestosis-associated deaths approximate the true occurrence of asbestosis between 1968 and 1990 as 41,000 (1,900 per year). Also, the studies of both Berry[21] and Coutts et al[22] determined that 39% of workers certified with asbestosis die of asbestos-related lung cancer. It follows that of the 41,000 individuals estimated as having asbestosis (between 1968 and 1990), approximately 16,000 of them died from asbestos-related lung cancer. Finally, the *Work-Related Lung Disease Surveillance Report*[20] determined that during this 22-year span, the total number of deaths from malignant pleural mesothelioma was 10,557. Adjusting this figure upward by 10% for additional cases of peritoneal origin,[23] the total number of malignant mesothelioma deaths during this period was around 12,000. Thus, between 1968 and 1990, the estimated total number of asbestos-related cancer deaths was 28,000 (1,300 per year).

The NIOSH surveillance data support the fact that while individuals clearly die of asbestos-related diseases, actual mortality figures suggest far smaller numbers than projected estimates have suggested. Also, due to inaccurate diagnoses, far fewer individuals probably have asbestos-related diseases than are implied by the number of personal injury claims that have been made. Consequently, greater specificity should be utilized in the clinical diagnosis of asbestos-related disorders. Becklake[24] feels this approach is particularly applicable when attempting to establish the presence of asbestosis for legal purposes. Arguments of legal attributability, which focus only on a few "selected" asbestosis criteria while negating or failing to consider others, lowers the predictability below acceptable standards for diagnosing asbestosis. Under such circumstances, the likelihood of an individual having asbestosis is too uncertain for sound legal or policy judgments.

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Diagnosis of Asbestosis*

Primum Non Nocere

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The preceding essay "Asbestos-Related Disorders: A Realistic Perspective" explores the diagnostic uncertainty confronting the clinician when asked by the asbestos-exposed patient, "Do I have asbestosis?"

Little has changed in diagnosis and treatment of

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asbestosis since 1986, when a committee of experts proposed useful clinical diagnostic criteria that did not require lung biopsy.[1] The most significant development over those 10 years has been the widespread availability of thin-section high-resolution CT of the chest. While providing a strikingly more detailed image of the lung parenchyma, high-resolution CT may not add diagnostic sensitivity or specificity for patients whose plain chest roentgenogram is on the borderline between normal and abnormal (International Labour Organization categories 0/1 to 1/0).[2] Unfortunately, it remains true in 1997 that we have no therapy to offer the patient with asbestosis, although rapid advances in the understanding of the basic pathogenesis holds promise for intervention trials in the near future.

A subcontext of this article is the frustration many pulmonologists feel in being called upon to make or exclude a diagnosis of asbestosis in patients whose disease is in a subclinical or very mild stage of progression. Like idiopathic pulmonary fibrosis, asbestosis begins as a silent alveolitis in the years after initial exposure. The alveolitis may be present and progressive for decades before it can be detected by symptoms, exam, roentgenogram, or lung function. Asbestosis characteristically progresses at a slow pace over decades, so that the clinical expression of an exposure in youth may not come until as late as the seventh or eighth decade. Unfortunately, there are also patients who progress much more rapidly. The factors that make one exposed individual progress to clinical asbestosis while his similarly exposed coworker remains apparently disease-free are currently being elucidated. A better understanding of cellular switching on the path from alveolitis to fibrosis may also lead to effective ways to modulate the lung's chronic inflammatory response to inhaled asbestos, thus providing a form of secondary prevention in the exposed individual without disease.

The legal culpability of several large asbestos manufacturing companies in actively suppressing scientific information about asbestos health effects over several decades produced outrage in thousands of employees exposed during those years. Many now seek out medical opinions to determine whether they qualify for compensation under class action lawsuits; others wish only to find out whether they are among the affected. A part of the frustration of clinicians stems from the difficult task of making a diagnosis in cases where the disease is still mild and the manifestations subtle. At this early stage of disease, diagnostic uncertainty is greater, and in the absence of treatment there is no clinical therapeutic advantage to be gained by early diagnosis, although many who are exposed desire prognostic information.

A major point raised is whether claims of asbestosis are being made in excess of the true number of cases of asbestosis and other asbestos-related diseases. This would seem to be an easy question to answer, but in fact it is not. It is appropriately pointed out that the number of cases determined depends on the sensitivity and specificity of the criteria used in a case definition. But for asbestosis in the United States, we have no accurate means to estimate the true prevalence of the disease. There are neither uniform diagnostic criteria nor specific surveillance programs designed to capture even a representative sample of cases. Hence, any estimates of the numbers of cases must be just that—estimates based on reasonable assumptions, but estimates that are not currently subject to verification. The estimate cited by the National Institute of Occupational Safety and Health (NIOSH) in the 1994 *Work-Related Lung Disease Surveillance Report*,[3] an authoritative resource on occupational lung disease and prevalence, is based on multiple cause of death data from the death certificates and collected from all reported deaths by the National Center for Health Statistics. The NIOSH authors caution that "limitations of multiple cause of death data include under- or over-reporting of conditions on the death certificate by certifying physicians."[3] Estimates of the national prevalence of asbestosis

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would need to be based on an estimate of the numbers of individuals with asbestos exposure and the time elapsed since exposure (because of the long latency). However, measurements of the prevalence of asbestosis in selected high-risk groups have been performed and are helpful in assessing the accuracy of the estimates.

One recent 56-center survey of asbestosis prevalence in building construction workers applied uniform diagnostic criteria in evaluating 9,605 asbestos-exposed sheet metal workers between 1986 and 1993 for whom at least 20 years had elapsed since entering the trade.[4] Among these volunteers, who may have self-selected according to their heavier exposure categories, the prevalence of parenchymal fibrosis was 12.3% or approximately 1,180 prevalent cases among those screened.

It is appropriately pointed out by Rosenberg that "without utilizing uniform criteria, occurrence data . . .are not comparable." The estimates of US asbestosis prevalence subsequent to this statement illustrate some of the pitfalls inherent in quick estimates of disease prevalence based on multiple unconnected databases.

Nevertheless, let us assume this estimate is true, and further assume that the number of legal claims outnumbers the cases of asbestosis. What is the appropriate medical response? To answer this question, we should return to the clinical setting and address the clinical question of diagnostic criteria for asbestosis in patients with an appropriate occupational exposure history. In this circumstance, our practice should be, as in all other situations, guided by informed clinical judgment. The expert panel[1] was as acutely aware of all these issues in 1986 as we are today, and wisely settled on a thorough but noninvasive evaluation which would be expected to have a high degree of sensitivity and specificity, recognizing that all tests have some false-positives and false-negatives. The expert panel pointed out that the more clinical criteria were met, the higher the sensitivity and specificity of the evaluation.

These clinical criteria were tested against the gold standard of lung biopsy, in the study by Gaensler et al.[5] The study found an approximately 5% false-positive rate for the clinical criteria, *ie*, that 95% of the clinically diagnosed cases did indeed have asbestosis, and 5% had other disease. The 95% specificity of the clinical criteria for asbestosis suggested by this study is consistent with the other literature on clinical diagnosis. Given this specificity, should we be recommending and performing open or thoracoscopic lung biopsies on more patients who ask the question, "Do I have asbestosis?" Does the number of asbestos-related personal injury claims provide a sound rationale for taking steps to improve the specificity of diagnosis from 95% up to 97 or 99%?

I would argue emphatically no, and for two reasons. The first is that a problem of overdiagnosis of asbestosis could be largely corrected simply by the more widespread application of the clinical diagnostic criteria. The problem of overdiagnosis, if it exists, is not any failure of these criteria, but only a failure to apply them. The second reason is that the use of more frequent invasive procedures would subject patients to the risks of general anesthesia and surgery without providing any clinical benefit. The surgical mortality of thoracoscopic lung biopsy is approximately 1%,[6] but it might be lower—approximately 0.5%—in patients with mild asbestosis. Surgical morbidity would be expected in the range of 5 to 10%. Such procedures would not improve quality of life or survival either in the 95% with asbestosis, or (because of the modest benefits of therapy in nonvasculitic interstitial disease) in the 5% with nonasbestos disease or no disease. The cost of each such thoracoscopic procedure at our institution is approximately $19,000. Who would pay these costs?

Good clinical practice requires attention to clinical features that may help in distinguishing a treatable pulmonary vasculitis from asbestosis. Such findings as systemic symptoms, renal disease, the presence of serologic markers of vasculitis, or even an unusually rapid progression may indicate a patient with a potentially treatable condition. By the same token, judicious clinical practice requires avoiding the risk of invasive procedures when the patient stands to gain no therapeutic benefit from the information added by biopsy. Our current approach to asbestosis diagnosis, given the limitations of our technology and therapy, is already quite realistic.

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REVIEW ARTICLES

CURRENT CONCEPTS

PULMONARY-FUNCTION TESTING

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PULMONARY-FUNCTION tests provide objective, quantifiable measures of lung function. They are used to evaluate and monitor diseases that affect heart and lung function, to monitor the effects of environmental, occupational, and drug exposures, to assess risks of surgery, and to assist in evaluations performed before employment or for insurance purposes. The indications for pulmonary-function tests are summarized in Table 1. Spirometric examination, the most widely used such test, is the focus of this paper. Spirometry is the measurement of the movement of air into and out of the lungs during various breathing maneuvers. Such examinations should be readily available and routinely used in medical offices and hospitals where patients with heart and lung diseases are treated. Other common tests of lung function include the measurement of lung volumes, airway resistance, carbon monoxide diffusing capacity, and arterial-blood gases.

Diagnostic Indications

Pulmonary-function tests are useful in diagnosing and managing pulmonary diseases. The recommendations of the National Asthma Education Program indicate that such testing is essential in the diagnosis and management of asthma because of evidence that both patients and physicians have inaccurate perceptions of the severity of asthma that contribute to delays in treatment.[1] Indeed, underestimation of the extent of airflow (airway) obstruction is associated with increased mortality in asthma.[2]

Pulmonary-function tests can identify abnormalities of lung function that might otherwise be overlooked and can exclude the possibility of some respiratory disorders such as chronic obstructive pulmonary disease. Physicians cannot identify obstructive or restrictive patterns reliably from history taking and physical examination alone.[3-5] When physicians ordering lung-function tests were asked to predict the results, they correctly predicted an obstructive pattern 83 percent of the time.[4] However, predictions of normal or restrictive patterns were correct only about half the time.[4] Besides identifying abnormalities, lung-function tests allow the severity of an abnormality to be quantified and the presence of reversible airflow obstruction to be determined.

Pulmonary-function testing is sometimes indicated when there may be more than one explanation for a patient's symptoms. For example, a smoker who presents with dyspnea and obvious signs of congestive heart failure may also have obstructive lung disease. Failure to recognize and treat both disorders may limit the therapeutic response.

Screening and Monitoring

Lung-function tests are included in many evaluations of fitness and some routine physical examinations. Such testing may provide interesting information, but in the absence of symptoms, physical findings, or risk factors its clinical usefulness is questionable. There is little evidence to support a policy of screening the general population with spirometry.[6] Some subgroups (e.g., cigarette smokers and people exposed to known agents of lung injury, such as asbestos or diisocyanates) are at higher risk of lung disease; screening and monitoring are appropriate for them.[5,7] It has been suggested that about 15 percent of cigarette smokers have an accelerated decline in the maximal volume of air exhaled, after a maximal inhalation, in the first second of a forced exhalation (i.e., the forced expiratory volume in one second, or FEV_1); ultimately, this condition leads to airflow obstruction and the possibility of early disability and death from chronic obstructive pulmonary disease.[8] Although the rates of loss of FEV_1 in smokers and nonsmokers overlap, nonsmokers tend to lose FEV_1 at a rate of 20 to 30 ml per year, whereas "sensitive" smokers (those with an accelerated decline in FEV_1) lose FEV_1 at a rate of more than 60 ml per year. In people under 35 years of age, cessation of smoking is associated with improved lung function; for those older than 35, the accelerated decline in lung function slows to the normal rate associated with aging.[8-10] Smokers with one normal spirogram cannot rest easy; they may still have an accelerated loss of lung function that is detectable only by serial measurements. Smokers may be more likely to stop smoking if they are informed of such functional abnormalities.

Serial measurement of lung function (monitoring) may be useful in tracking pulmonary expressions of diseases, quantifying responses to therapy, and making early diagnoses of lung injury after occupational exposures and drug or radiation therapy. Many diseases, including heart failure, rheumatoid arthritis, inflammatory bowel disease, and vasculitis, affect the lungs either directly or as a result of the adverse effects of treatment.[11] Monitoring lung function allows the physician to identify and quantify pulmonary involvement in such diseases. For example, serial measurement of vital capacity (VC) may help a physician

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Table 1. Indications for Pulmonary-Function Tests.

Diagnostic

To evaluate symptoms, signs, and abnormal results of laboratory tests
- Symptoms: cough, dyspnea, wheezing, orthopnea, or chest pain
- Signs: overinflation, expiratory slowing, cyanosis, chest deformity, wheezing, or unexplained crackles
- Abnormal results of laboratory tests: hypoxemia, hypercapnia, polycythemia, or abnormal chest radiographs

To measure the effect of disease on pulmonary function

To screen persons at risk for pulmonary disease
- Smokers
- Persons with occupational exposure to injurious substances
- Some persons at the time of a routine physical examination

To assess preoperative risk

To assess prognosis

Monitoring

To assess effectiveness of therapeutic interventions
- Bronchodilator therapy
- Steroid treatment for asthma, interstitial lung disease, and the like
- Management of congestive heart failure
- Other

To provide information on the course of diseases affecting lung function
- Pulmonary disease, such as obstructive airways disease and interstitial lung disease
- Cardiac disease, such as congestive heart failure
- Neuromuscular disease, such as Guillain–Barré syndrome

To assess current status of persons with occupational exposure to injurious substances

To detect adverse reactions to drugs with known pulmonary toxicity

Evaluation of disability or impairment

To assess patients as part of a rehabilitation program
- Medical
- Industrial
- Vocational

To assess risks for an insurance evaluation

To assess the condition of persons for legal reasons
- Social security or other program involving government compensation
- Personal-injury lawsuits
- Other

Public health

Epidemiologic surveys

quantify a patient's response to therapeutic agents in congestive heart failure. In the Framingham study, decreases in VC were a better predictor of heart failure than were symptoms, examinations, or radiographic findings.[12] Improvements in VC may also indicate recovery from congestive heart failure.[13]

Numerous drugs are associated with lung injury.[14,15] The role of pulmonary-function testing in monitoring for drug toxicity is not clearly defined. In the case of amiodarone hydrochloride, an antiarrhythmic agent, it is quite controversial, but monitoring of lung function may confirm or provide an early indication that an adverse pulmonary reaction has begun. The development of pulmonary fibrosis can be monitored with lung-function testing in patients undergoing cancer chemotherapy or radiation therapy involving lung parenchyma. Lung-transplant recipients are commonly monitored with lung-function tests to detect early evidence of bronchiolitis obliterans.[16,17]

Monitoring is useful only when adequate base-line studies are available for comparison. A change from a patient's base-line value is more likely to indicate pulmonary injury than is the traditional comparison of values measured in the patient with reference values obtained from population studies. Changes from base line that are as small as 5 to 10 percent may be substantial for a person and could be missed if only reference values are used in the comparison. Consider, for example, a 40-year-old man who is 175 cm tall. His predicted VC, based on reference values, is 4.99 liters (normal range, 3.79 to 6.11). If his VC at base line was 6 liters, it could decrease by up to 37 percent before his test results fell below the normal range.

The frequency and kinds of pulmonary-function tests vary with the situation. If the primary involvement is in the airways (for example, in a lung-transplant recipient at risk of bronchiolitis obliterans), spirometric testing is adequate. If involvement of the lung parenchyma is likely (for example, in a patient receiving bleomycin), lung volumes and the carbon monoxide diffusing capacity (DLCO; also known, especially in Europe, as "transfer factor") should also be measured. In congestive heart failure, lung volumes are primarily affected, and VC is the best index to monitor.

Preoperative Evaluation

Although the role of preoperative pulmonary-function testing remains controversial,[18] its goals are now more clearly defined.[19-21] They include helping to identify patients for whom the risk of surgery is prohibitive and helping to identify patients at increased risk of pulmonary complications, for whom better-informed decisions about preoperative and postoperative care can then be made.

There is general agreement that at the least, the preoperative pulmonary testing of patients for whom lung resection is being considered should include spirometry and measurement of arterial-blood gases. The abnormalities that suggest an increased risk of postoperative pulmonary complications and the need for further evaluation are as follows: VC less than 50 percent of the predicted value, FEV_1 less than 2 liters or less than 50 percent of predicted, or the presence of substantial hypoxemia or hypercapnia. Studies designed to predict postoperative FEV_1 from ventilation or perfusion scans and, in some cases, DLCO and exercise studies may help in further defining the risk.[19-21] Patients whose predicted postoperative FEV_1 is less than 0.8 liter or 40 percent of the predicted value are at very high risk.

For other surgery, the risk of postoperative pulmonary complications generally declines as the distance from the chest to the surgical site increases. Upper abdominal and thoracic operations not involving lung resection are associated with increased risks of pulmonary complications. Smokers and people with signs and symptoms suggestive of lung disease are most likely to benefit from preoperative screening with spirometry and blood gas analysis.[21] Lower abdominal and head-and-neck surgery are associated with lower surgical risks. Spirometric testing and blood gas analysis are likely to help only patients without prior lung-function tests whose preoperative evaluation suggests the presence of pulmonary disease.[21]

Risk and Prognosis in Patients with Known Lung Dysfunction

Low levels of lung function, even in patients who have never smoked cigarettes, are associated with a poor prognosis in patients with heart and lung disease. Studies consistently find that reduced lung function (usually FEV_1) is associated with an increased risk of death from chronic obstructive pulmonary disease, non-neoplastic respiratory diseases, vascular diseases, lung cancer, and all causes of death considered together.[22-25] These findings are consistent among groups of patients, but it is not possible to predict the symptoms or mortality of individual patients accurately on the basis of FEV_1 alone.

Interpretation of Lung-Function Tests

Test quality remains the most important concern in lung-function testing. Variability (noise) is greater in pulmonary-function tests than in most other clinical laboratory tests because of the inconsistency of efforts by patients.[26] The American Thoracic Society (ATS), the European Respiratory Society, and other organizations have published standards designed to minimize the variability in these tests[27-44] (Table 2). The elements that lead to high-quality test results are accurate equipment, good test procedures, an ongoing program of quality control, appropriate reference values, and good algorithms for the interpretation of results. It is tempting to assume that all equipment on the market is accurate. However, a 1990 evaluation of spirometers revealed that only 57 percent met the standards of the ATS for accuracy.[42] Purchasers should insist on evidence that an instrument meets the ATS performance recommendations.[27] A quality-control program for spirometers that uses a calibrated 3.0-liter syringe and a few other simple checks[32] can be conducted easily in a physician's office. Monitoring the accuracy of instruments that measure diffusing capacity, lung volume, and blood gases is more difficult. These machines are best used in settings where there are larger volumes of patients.

The interpretation of lung-function tests usually involves comparing values measured in patients with reference values from studies of populations of healthy nonsmokers. There are substantial differences between the equations used to predict normal lung function, because of differences among the populations studied as well as technical and procedural differences. It is important to select equations for reference use that are well matched with the patients served in a particular office or laboratory. The ATS has published guidelines for making these choices.[33] Physicians unfamiliar with selecting reference values and choosing the lower limits of normal ranges should consult a local pulmonary-testing laboratory with expertise in this area.

The first step in interpreting a lung-function test is to assess and comment on test quality. Spirometric tracings should be examined to make sure they represent adequate effort by the patient, are reproducible, and contain no artifacts that would alter the test results (Table 3). If the requirements for quality are not met, tests should be interpreted (Table 4) with caution. Some technical problems are so important that

Table 2. Sources of Information on the Measurement and Interpretation of Pulmonary-Function Tests.

Type of Information	Reference
Adults	
Practical, how-to manuals or guides	Morris et al.,[38] Enright and Hyatt,[40] Miller,[39] Wanger,[41] Clausen[37]
Standards	
Equipment and procedures	
Spirometry	American Thoracic Society,[27] European Respiratory Society,[28] Morris et al.,[38] Nelson et al.[42]
DLCO	American Thoracic Society,[29] European Respiratory Society[28]
Lung volumes and mechanics	European Respiratory Society[28]
Personnel	Gardner et al.[30]
Computers	Gardner et al.[31]
Quality control	Gardner et al.,[32] Clausen[37]
Reference values and interpretation	American Thoracic Society,[33] European Respiratory Society,[28] Morris et al.,[38] Clausen[37]
Disability or impairment	American Medical Association,[43] American Thoracic Society[44]
Children	
Overall guidelines	Quanjer et al.,[34] Taussig et al.,[35] Zapletal et al.[36]

Table 3. Technical Requirements for Spirometry of Good Quality.*

At least 3 acceptable tests
Full inhalation before start of test
Satisfactory start of exhalation
Evidence of maximal effort
No hesitation
No cough or glottal closure during the first second
Satisfactory duration of test
At least 6 seconds
Up to 15 seconds in patients with airflow obstruction
No evidence of leak
No evidence of obstruction of the mouthpiece
Reproducible results
For FVC and FEV_1, the 2 largest values should be within 5 percent or 0.1 liter (whichever is larger) of each other
If these criteria are not met, continue testing
If the criteria are not met after 8 trials, stop testing and proceed with the interpretation, using the 3 best acceptable tests
Selection of test values for interpretation
Select from tests of acceptable quality
Select the largest values for FVC and FEV_1, regardless of the test used
For indexes of average or instantaneous flow, use values from the test with the largest value for FVC and FEV_1 combined

*Adapted from the statement of the American Thoracic Society,[27] with the permission of the publisher.

they prevent any interpretive statements from being made: other problems reduce but do not totally eliminate the amount of interpretable information. For example, a set of spirograms may contain good information about VC but not about FEV_1.

Figures 1 and 2 show spirograms from a normal subject and two patients with airflow obstruction. With computerized equipment, more than 20 different spirometric variables can be reported. It is important to resist the temptation to use more than a few such variables in the basic interpretation. Increasing the number of variables used in the test increases the number of false positive results.[33] In spirometry, there are several basic variables. VC is the maximal volume of air that can be exhaled after a maximal inhalation or the maximal volume of air that can be inhaled after a maximal exhalation. It can be measured as two variables: forced vital capacity (FVC) and slow vital capacity (SVC). Two other variables are FEV_1 and FEV_1/VC% (calculated as $FEV_1/VC \times 100$). In most cases these variables suffice to provide all the information needed to interpret a spirogram.

Two basic types of lung dysfunction can be defined by spirometry: obstructive patterns and restrictive patterns. The primary criterion for airflow obstruction is a reduced FEV_1/VC%. Other measurements of flow can be used to support conclusions based on this variable or to assist in making decisions when FEV_1/VC% is borderline.

A restrictive pattern means that lung volumes are small. The primary criterion for this diagnosis is a reduction in total lung capacity (TLC), the volume of air in the lungs at the end of a maximal inhalation. However, the presence of restriction is commonly inferred from a decreased VC. VC may also be reduced in the presence of airflow obstruction, especially when exhalation time is short. When there is airflow obstruction and VC is reduced, the possibility of restriction can usually be eliminated with evidence of overinflation from the physical examination or chest radiograph. When there is any question about the cause of a reduced VC, TLC should be measured. Even though restriction is defined by a reduced TLC, VC has frequently been demonstrated to be more useful in following the course of restrictive chest diseases.

Table 5 lists the criteria of the ATS for evaluating a response to the administration of a bronchodilator in the laboratory and assessing the importance of

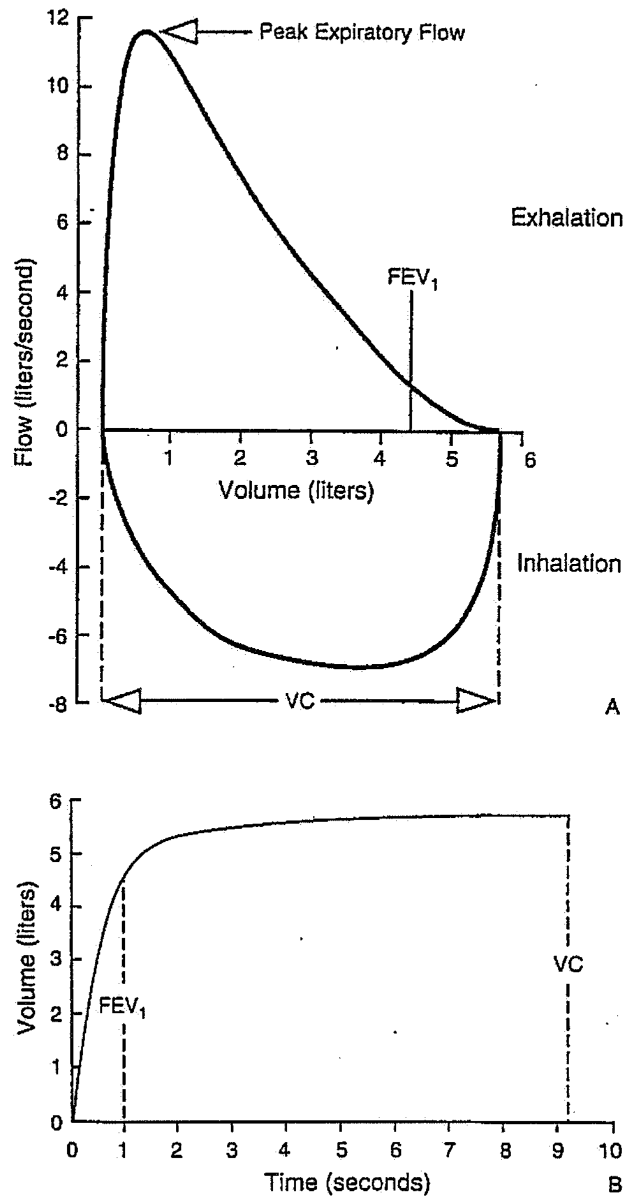

Figure 1. Spirometric Flow–Volume (Panel A) and Volume–Time (Panel B) Curves for a Healthy 52-Year-Old Man 188 cm Tall.

In the flow–volume curve the well-defined peak in expiratory flow shows good initial effort. The slightly concave appearance of the expiratory portion of the curve appears with aging alone. In a 20-year-old person, the same pattern could indicate the presence of airflow obstruction. In the volume–time curve good initial effort is shown by the sharp increase in volume from time zero. The long, slow increase in volume shows the age-related decrease in flow at end-expiration. Total expiratory time can be seen only in the volume–time curve.

Table 4. Guidelines for the Interpretation of Spirometry.*

Choose statistically acceptable lower limits of normal.
Evaluate and comment on test quality.
Use FVC, FEV_1, and FEV_1/VC% as the primary guides for interpretation. (Increasing the number of variables in the interpretation increases the incidence of false positive results.)
Values that are well above or well below the lower limits of normal can be interpreted with confidence. Interpret borderline values with caution, using clinical information to make decisions.
The primary indicator of airflow obstruction is a reduced FEV_1/VC%.
Once obstruction is diagnosed, classify the severity using FEV_1 expressed as a percentage of the predicted value.
Determine the response to bronchodilator therapy (see Table 5).
A restrictive pattern may be cautiously diagnosed from the spirometric examination when VC is reduced and FEV_1/VC% is normal. However, the definitive finding for a restrictive pattern is a reduced TLC.
The severity of restriction should be based on TLC if that value is available, and otherwise from VC.
Restriction cannot be diagnosed from the spirometric examination in the presence of moderate-to-severe airflow obstruction.

*Adapted from the statement of the American Thoracic Society,[33] with the permission of the publisher.

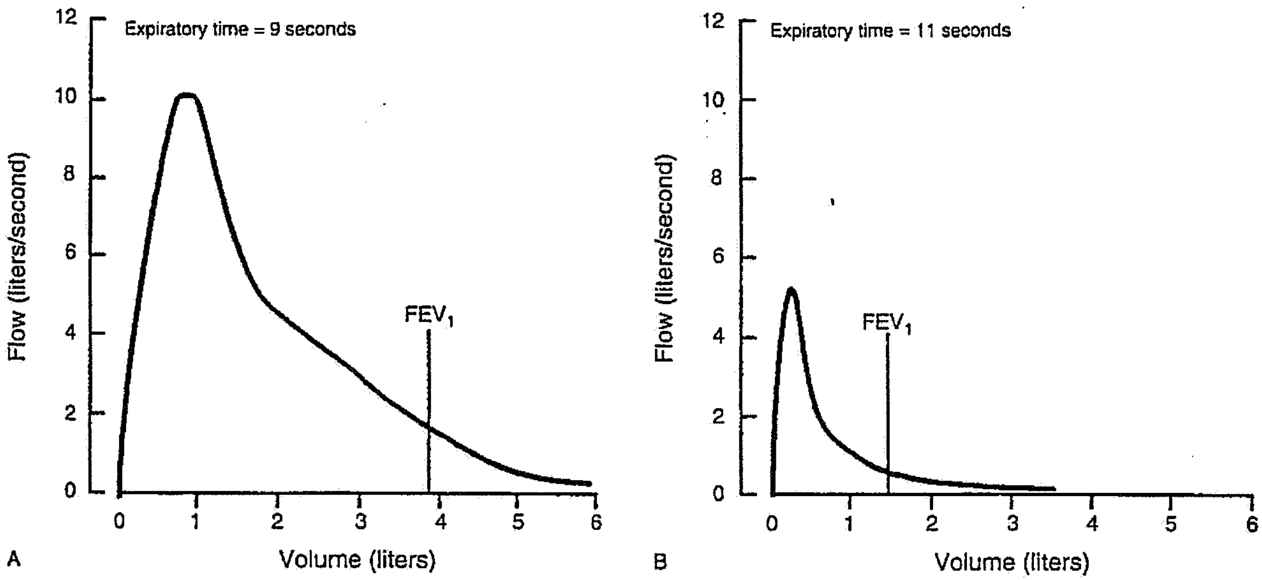

Figure 2. Expiratory Flow–Volume Curves for Patients with Mild and Severe Airflow Obstruction.

Panel A shows the curve for a 45-year-old man 184 cm tall with mild airflow obstruction. The initial effort is good, with early, well-defined peak expiratory flow. The concave character of the descending curve indicates the presence of airflow obstruction. FEV_1/VC% is reduced at 64 (predicted value, 80), but FEV_1 is normal (92 percent of predicted), indicating that the obstruction is mild. The expiratory flow approaches but does not reach zero, a subtle but important element to look for on the tracing; it may be the only evidence of a problem with the test, because total expiratory time is not seen on the flow–volume curve.

Panel B shows the curve for a 47-year-old man 183 cm tall with severe airflow obstruction. Although peak expiratory flow is reduced, the peak is well defined, indicating a good initial effort. There is a sudden drop in flow after the peak, and the tail of the expiration curve is long. The subject's FEV_1/VC% is 40. The marked reduction in FEV_1 (34 percent of predicted) indicates the presence of severe airflow obstruction.

changes in FVC and FEV_1 over time.[33] Treating a patient with a bronchodilator medication is a clinical, not a laboratory, decision. A response to this therapy in the laboratory makes a clinical response to therapy more likely; nevertheless, the lack of such a response does not preclude a clinical response to long-term bronchodilator therapy. If the clinical evaluation suggests that such therapy may be effective, it can be instituted and followed by a reevaluation, both clinical and spirometric, in four to six weeks. As when patients are monitored in other ways, patterns of change are more apparent with serial measurements.

Table 5. Response to Bronchodilator Therapy and Changes over Time.*

Measure of Response	Percent Change in FVC or FEV_1 Required for a Substantial Response†	Comment
Current ATS recommendation	12	Both a 12 percent improvement and an absolute improvement of 200 ml are required.
Change from week to week		
Normal subjects	≥12	
Patients with chronic obstructive pulmonary disease	≥20	

*Adapted from the statement of the American Thoracic Society,[33] with the permission of the publisher.

†Changes in FVC must not be due to a longer total exhalation time in persons with airflow obstruction.

Classifying the severity of disease involves several complex issues. A general discussion and specific guidelines are provided in the statement by the ATS.[33]

Conclusions

There are good reasons to seek quantifiable data about lung function. Interpreting the results of pulmonary-function testing requires careful attention to the equipment used, the patient's performance, and the reference values chosen. In cases in which disease or lung injury may develop over time, a person's own base-line values provide the best reference data.

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1910.1043—COTTON DUST

(a) Scope and application.

(1) This section, in its entirety, applies to the control of employee exposure to cotton dust in all workplaces where employees engage in yarn manufacturing, engage in slashing and weaving operations, or work in waste houses for textile operations.

(2) This section does not apply to the handling or processing of woven or knitted materials; to maritime operations covered by 29 CFR Parts 1915 and 1918; to harvesting or ginning of cotton; or to the construction industry.

(3) Only paragraphs (h) Medical surveillance, (k)(2)-(4) Recordkeeping—Medical Records, and Appendices B, C and D of this section apply in all work places where employees exposed to cotton dust engage in cottonseed processing or waste processing operations.

(4) This section applies to yarn manufacturing and slashing and weaving operations exclusively using washed cotton (as defined by paragraph (n) of this section) only to the extent specified by paragraph (n) of this section.

(5) This section, in its entirety, applies to the control of all employees exposure to the cotton dust generated in the preparation of washed cotton from opening until the cotton is thoroughly wetted.

(6) This section does not apply to knitting, classing or warehousing operations except that employers with these operations, if requested by NIOSH, shall grant NIOSH access to their employees and workplaces for exposure monitoring and medical examinations for purposes of a health study to be performed by NIOSH on a sampling basis.

(b) Definitions. For the purpose of this section:

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Blow down" means the general cleaning of a room or a part of a room by the use of compressed air.

"Blow off" means the use of compressed air for cleaning of short duration and usually for a specific machine or any portion of a machine.

"Cotton dust" means dust present in the air during the handling or processing of cotton, which may contain a mixture of many substances including ground up plant matter, fiber, bacteria, fungi, soil, pesticides, non-cotton plant matter and other contaminants which may have accumulated with the cotton during the growing, harvesting and subsequent processing or storage periods. Any dust present during the handling and processing of cotton through the weaving or knitting of fabrics, and dust present in other operations or manufacturing processes using raw or waste cotton fibers or cotton fiber byproducts from textile mills are considered cotton dust within this definition. Lubricating oil mist associated with weaving operations is not considered cotton dust.

"Director" means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

"Equivalent Instrument" means a cotton dust sampling device that meets the vertical elutriator equivalency requirements as described in paragraph (d)(1)(iii) of this section.

"Lint-free respirable cotton dust" means particles of cotton dust of approximately 15 micrometers or less aerodynamic equivalent diameter.

"Vertical elutriator cotton dust sampler" or "vertical elutriator" means a dust sampler which has a particle size cut-off at approximately 15 micrometers aerodynamic equivalent diameter when operating at the flow rate of 7.4 ± 0.2 liters of air per minute.

"Waste processing" means waste recycling (sorting, blending, cleaning and willowing) and garnetting.

"Yarn manufacturing" means all textile mill operations from opening to, but not including, slashing and weaving.

(c) Permissible exposure limits and action levels.

(1) Permissible exposure limits.

(i) The employer shall assure that no employee who is exposed to cotton dust in yarn manufacturing and cotton washing operations is exposed to airborne concentrations of lint-free respirable cotton dust greater than 200 $\mu g/m^3$ mean concentration, averaged over an eight-hour period, as measured be a vertical elutriator or an equivalent instrument.

(ii) The employer shall assure that no employee who is exposed to cotton dust in textile mill waste house operations or is exposed in yarn manufacturing to dust from "lower grade washed cotton" as defined in paragraph (n)(5) of this section is exposed to airborne concentrations of lint-free respirable cotton dust greater than 500 $\mu g/m^3$ mean concentration, averaged over an eight-hour period, as measured by a vertical elutriator or an equivalent instrument.

(iii) The employer shall assure that no employee who is exposed to cotton dust in the textile processes known as slashing and weaving is exposed to airborne concentrations of lint-free respirable cotton dust greater than 750 $\mu g/m^3$ mean concentration, averaged over an eight hour period, as measured by a vertical elutriator or an equivalent instrument.

(2) Action levels.

(i) The action level for yarn manufacturing and cotton washing operations is an airborne concentration of lint-free respirable cotton dust of 100 $\mu g/m^3$ mean concentration, averaged over an eight-hour period, as measured by a vertical elutriator or an equivalent instrument.

(ii) The action level for waste houses for textile operations is an airborne concentration of lint-free respirable cotton dust of 250 $\mu g/m^3$ mean concentration, averaged over an eight-hour period, as measured by a vertical elutriator or an equivalent instrument.

(iii) The action level for the textile processes known as slashing and weaving is an airborne concentration of lint-free respirable cotton dust of 375 $\mu g/m^3$ mean concentration, averaged over an eight-hour period, as measured by a vertical elutriator or an equivalent instrument.

(d) Exposure monitoring and measurement.

(1) General.

(i) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(ii) The sampling device to be used shall be either the vertical elutriator cotton dust sampler or an equivalent instrument.

(iii) If an alternative to the vertical elutriator cotton dust sampler is used, the employer shall establish equivalency by reference to an OSHA opinion or by documenting, based on data developed by the employer or supplied by the manufacturer, that the alternative sampling devices meets the following criteria:

(a) It collects respirable particulates in the same range as the vertical elutriator (approximately 15 microns);

(b) Replicate exposure data used to establish equivalency are collected in side-by-side field and laboratory comparisons; and

(c) A minimum of 100 samples over the range of 0.5 to 2 times the permissible exposure limit are collected, and 90% of these samples have an accuracy range of plus or minus 25 percent of the vertical elutriator reading with a 95% confidence level as demonstrated by a statistically valid protocol. (An acceptable protocol for demonstrating equivalency is described in Appendix E of this section.)

(iv) OSHA will issue a written opinion stating that an instrument is equivalent to a vertical elutriator cotton dust sampler if:

(a) A manufacturer or employer requests an opinion in writing and supplies the following information:

(1) Sufficient test data to demonstrate that the instrument meets the requirements specified in this paragraph and the protocol specified in Appendix E of this section;

(2) Any other relevant information about the instrument and its testing requested by OSHA; and

(3) A certification by the manufacturer or employer that the information supplied is accurate; and

(b) If OSHA finds, based on information submitted about the instrument, that the instrument meets the requirements for equivalency specified by paragraph (d) of this section.

(2) Initial monitoring. Each employer who has a place of employment within the scope of paragraph (a)(1), (a)(4), or (a)(5) of this section shall conduct monitoring by obtaining measurements which are representative of the exposure of all employees to airborne concentrations of lint-free respirable cotton dust over an eight-hour period. The sampling program shall include at least one determination during each shift for each work area.

(3) Periodic monitoring.

(i) If the initial monitoring required by paragraph (d)(2) of this section or any subsequent monitoring reveals employee exposure to be at or below the permissible exposure limit, the employer shall repeat the monitoring for those employees at least annually.

(ii) If the initial monitoring required by paragraph (d)(2) of this section or any subsequent monitoring reveals employee exposure to be above the PEL, the employer shall repeat the monitoring for those employees at least every six months.

(iii) Whenever there has been a production, process, or control change which may result in new or additional exposure to cotton dust, or whenever the employer has any other reason to suspect an increase in employee exposure, the employer shall repeat the monitoring and measurements for those employees affected by the change or increase.

(4) Employee notification.

(i) Within twenty working days after the receipt of monitoring results, the employer shall notify each employee in writing of the exposure measurements which represent that employee's exposure.

(ii) Whenever the results indicate that the employee's exposure exceeds the applicable permissible exposure limit specified in paragraph (c) of this section, the employer shall include in the written notice a statement that the permissible exposure limit was exceeded and a description of the corrective action taken to reduce exposure below the permissible exposure limit.

(e) Methods of compliance.

(1) Engineering and work practice controls. The employer shall institute engineering and work practice controls to reduce and maintain employee exposure to cotton dust at or below the permissible exposure limit specified in paragraph (c) of this section, except to the extent that the employer can establish that such controls are not feasible.

(2) Whenever feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the permissible exposure limit, the employer shall nonetheless institute these controls to reduce exposure to the lowest feasible level, and shall supplement these controls with the use of respirators which shall comply with the provisions of paragraph (f) of this section.

(3) Compliance program.

(i) Where the most recent exposure monitoring data indicates that any employee is exposed to cotton dust levels greater than the permissible exposure limit, the employer shall establish and implement a written program sufficient to reduce exposures to or below the permissible exposure limit solely by means of engineering controls and work practices as required by paragraph (e)(1) of this section.

(ii) The written program shall include at least the following:

(a) A description of each operation or process resulting in employee exposure to cotton dust at levels greater than the PEL;

(b) Engineering plans and other studies used to determine the controls for each process;

(c) A report of the technology considered in meeting the permissible exposure limit;

(d) Monitoring data obtained in accordance with paragraph (d) of this section;

(e) A detailed schedule for development and implementation of engineering and work practice controls, including exposure levels projected to be achieved by such controls;

(f) Work practice program; and

(g) Other relevant information.

(iii) The employer's schedule as set forth in the compliance program, shall project completion of the implementation of the compliance program no later than March 27, 1984 or as soon as possible if monitoring after March 27, 1984 reveals exposures over the PEL, except as provided in paragraph (m)(2)(ii)(B) of this section.

(iv) The employer shall complete the steps set forth in his program by the dates in the schedule.

(v) Written programs shall be submitted, upon request, to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, and any affected employee or their designated representatives.

(vi) The written program required under paragraph (e)(3) of this section shall be revised and updated when necessary to reflect the current status of the program and current exposure levels.

(4) Mechanical ventilation. When mechanical ventilation is used to control exposure, measurements which demonstrate the effectiveness of the system to control exposure, such as capture velocity, duct velocity, or static pressure shall be made at reasonable intervals.

(f) Use of respirators.

(1) General. Where the use of respirators is required under this section, the employer shall provide, at no cost to the employee, and assure the use of respirators which comply with the requirements of this paragraph (f). Respirators shall be used in the following circumstances:

(i) During the time periods necessary to install or implement feasible engineering controls and work practice controls;

(ii) During maintenance and repair activities in which engineering and work practice controls are not feasible;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limits;

(iv) In operations specified under paragraph (g)(1) of this section; and

(v) Whenever an employee requests a respirator.

(2) Respirator selection.

(i) Where respirators are required under this section, the employer shall select the appropriate respirator from Table I below and shall assure that the employee uses the respirator provided.

TABLE I

Cotton dust concentration	Required respirator
Not greater than:	
(a) 5 × the applicable permissible exposure limit (PEL).	A disposable respirator with a particulate filter.
(b) 10 × the applicable PEL.	A quarter or half-mask respirator, other than a disposable respirator, equipped with particulate filters.
(c) 100 × the applicable PEL.	A full facepiece respirator equipped with high-efficiency particulate filters.
(d) Greater than 100 × the applicable PEL.	A powered air-purifying respirator equipped with high-efficiency particulate filters.

NOTES

1. A disposable respirator means the filter element is an inseparable part of the respirator.

2. Any respirators permitted at higher environmental concentrations can be used at lower concentrations.

3. Self-contained breathing apparatus are not required respirators but are permitted respirators.

4. Supplied air respirators are not required but are permitted under the following conditions: Cotton dust concentration not greater than 10x the PEL—Any supplied air respirator; not greater than 100x the PEL—Any supplied air respirator; with full facepiece, helmet or hood; greater than 100x the PEL—A supplied air respirator operated in positive pressure mode.

(ii) The employer shall select respirators from those tested and approved for protection against dust by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR Part 11.

(iii) Whenever respirators are required by this section for concentrations not greater than 100 × the applicable permissible exposure limit, the employer shall, upon the request of the employee, provide a powered air purifying respirator with a high efficiency particulate filter in lieu of the respirator specified in paragraphs (a), (b), or (c) of Table I.

(iv) Whenever a physician determines that an employee who works in an area in which the dust level exceeds the PEL is unable to wear any form of respirator, including a powered air purifying respirator, the employee shall be given the opportunity to transfer to another position which is available or which later becomes available having a dust level at or below the PEL. The employer shall assure that an employee who is transferred from an area in which the dust level exceeds the PEL due to an inability to wear a respirator suffers no reduction in current wage rate or other benefits as a result of the transfer.

(3) Respirator program. The employer shall institute a respirator program in accordance with § 1910.134 of this part.

(4) Respirator usage.

(i) The employer shall assure that the respirator used by each employee exhibits minimum facepiece leakage and that the respirator is fitted properly.

(ii) The employer shall allow each employee who uses a filter respirator, to change the filter elements whenever an increase in breathing resistance is detected by the employee. The employer shall maintain an adequate supply of filter elements for this purpose.

(iii) The employer shall allow employees who wear respirators to wash their faces and respirator face pieces to prevent skin irritation associated with respirator use.

(g) Work practices. Each employer shall, regardless of the level of employee exposure, immediately establish and implement a written program of work practices which shall minimize cotton dust exposure. The following shall be included were applicable:

(1) Compressed air "blow down" cleaning shall be prohibited where alternative means are feasible. Where compressed air is used for cleaning, the employees performing the "blow down" or "blow off" shall wear suitable respirators. Employees whose presence is not required to perform "blow down" or "blow off" shall be required to leave the area affected by the "blow down" or "blow off" during this cleaning operation.

(2) Cleaning of clothing or floors with compressed air shall be prohibited.

(3) Floor sweeping shall be performed with a vacuum or with methods designed to minimize dispersal of dust.

(4) In areas where employees are exposed to concentrations of cotton dust greater than the permissible exposure limit, cotton and cotton waste shall be stacked, sorted, baled, dumped, removed or otherwise handled by mechanical means, except where the employer can show that it is infeasible to do so. Where infeasible, the method used for handling cotton and cotton waste shall be the method which reduces exposure to the lowest level feasible.

(h) Medical surveillance.

(1) General.

(i) Each employer covered by the standard shall institute a program of medical surveillance for all employees exposed to cotton dust.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician and are provided without cost to the employee.

(iii) Persons other than licensed physicians, who administer the pulmonary function testing required by this section shall have completed a NIOSH-approved training course in spirometry.

(2) Initial examinations. The employer shall provide medical surveillance to each employee who is or may be exposed to cotton dust. For new employees, this examination shall be provided prior to initial assignment. The medical surveillance shall include at least the following:

(i) A medical history;

(ii) The standardized questionnaire contained in Appendix B; and

(iii) A pulmonary function measurement, including a determination of forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1), the FEV_1/FVC ratio, and the percentage that the measured values of FEV_1 and FVC differ from the predicted values, using the standard tables in Appendix C. These determinations shall be made for each employee before the employee enters the workplace on the first day of the work week, preceded by at least 35 hours of no exposure to cotton dust. The tests shall be repeated during the shift, no less than 4 and no more than 10 hours after the beginning of the work shift; and, in any event, no more than one hour after cessation of exposure. Such exposure shall be typical of the employee's usual workplace exposure. The predicted FVE_1, FEV, and FVC for blacks shall be multiplied by 0.85 to adjust for ethnic differences.

(iv) Based upon the questionnaire results, each employee shall be graded according to Schilling's byssinosis classification system.

(3) Periodic examinations.

(i) The employer shall provide at least annual medical surveillance for all employees exposed to cotton dust above the action level in yarn manufacturing, slashing and weaving, cotton washing and waste house operations. The employer shall provide medical surveillance at least every two years for all employees exposed to cotton dust at or below the action level, for all employees exposed to cotton dust from washed cotton (except from washed cotton defined in paragraph (n)(3) of this section), and for all employees exposed to cotton dust in cottonseed processing and waste processing operations. Periodic medical surveillance shall include at least an update of the medical history, standardized questionnaire (App. B-111), Schilling byssinosis grade, and the pulmonary function measurements in paragraph (h)(2)(iii) of this section.

(ii) Medical surveillance as required in paragraph (h)(3)(i) of this section shall be provided every six months for all employees in the following categories:

(a) An FEV_1 of greater than 80 percent of the predicted value, but with an FEV_1 decrement of 5 percent or 200 ml. on a first working day;

(b) An FEV_1 of less than 80 percent of the predicted value; or

(c) Where, in the opinion of the physician, any significant change in questionnaire findings, pulmonary function results, or other diagnostic tests have occurred.

(iii) An employee whose FEV_1 is less than 60 percent of the predicted value shall be referred to a physician for a detailed pulmonary examination.

(iv) A comparison shall be made between the current examination results and those of previous examinations and a determination made by the physician as to whether there has been a significant change.

(4) Information provided to the physician. The employer shall provide the following information to the examination physician:

(i) A copy of this regulation and its Appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's exposure level or anticipated exposure level;

(iv) A description of any personal protective equipment used or to be used; and

(v) Information from previous medical examinations of the affected employee which is not readily available to the examining physician.

(5) Physician's written opinion.

(i) The employer shall obtain and furnish the employee with a copy of a written opinion from the examining physician containing the following:

(a) The results of the medical examination and tests including the FEV_1, FVC, AND FEV_1/FVC ratio;

(b) The physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of the employee's health from exposure to cotton dust;

(c) The physician's recommended limitations upon the employee's exposure to cotton dust or upon the employee's use of respirators including a determination of whether an employee can wear a negative pressure respirator, and where the employee cannot, a determination of the employee's ability to wear a powered air purifying respirator; and,

(d) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The written opinion obtained by the employer shall not reveal specific findings or diagnoses unrelated to occupational exposure.

(i) Employee education and training.

(1) Training program.

(i) The employer shall provide a training program for all employees exposed to cotton dust and shall assure that each employee is informed of the following:

(a) The acute and long term health hazards associated with exposure to cotton dust;

(b) The names and descriptions of jobs and processes which could result in exposure to cotton dust at or above the PEL.

(c) The measures, including work practices required by paragraph (g) of this section, necessary to protect the employee from exposures in excess of the permissible exposure limit;

(d) The purpose, proper use and limitations of respirators required by paragraph (f) of this section;

(e) The purpose for and a description of the medical surveillance program required by paragraph (h) of this section and other information which will aid exposed employees in understanding the hazards of cotton dust exposure; and

(f) The contents of this standard and its appendices.

(ii) The training program shall be provided prior to initial assignment and shall be repeated annually for each employee exposed to cotton dust, when job assignments or work processes change and when employee performance indicates a need for retraining.

(2) Access to training materials.

(i) Each employer shall post a copy of this section with its appendices in a public location at the workplace, and shall, upon request, make copies available to employees.

(ii) The employer shall provide all materials relating to the employee training and information program to the Assistant Secretary and the Director upon request.

(j) Signs. The employer shall post the following warning sign in each work area where the permissible exposure limit for cotton dust is exceeded:

WARNING

COTTON DUST WORK AREA

MAY CAUSE ACUTE OR DELAYED

LUNG INJURY

(BYSSINOSIS)

RESPIRATORS

REQUIRED IN THIS AREA

(k) Recordkeeping.

(1) Exposure measurements.

(i) The employer shall establish and maintain an accurate record of all measurements required by paragraph (d) of this section.

(ii) The record shall include:

(a) A log containing the items listed in paragraph IV (a) of Appendix A, and the dates, number, duration, and results of each of the samples taken, including a description of the procedure used to determine representative employee exposure;

(b) The type of protective devices worn, if any, and length of time worn; and

(c) The names, social security numbers, job classifications, and exposure levels of employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 20 years.

(2) Medical surveillance.

(i) The employer shall establish and maintain an accurate medical record for each employee subject to medical surveillance required by paragraph (h) of this section.

(ii) The record shall include:

(a) The name and social security number and description of the duties of the employee;

(b) A copy of the medical examination results including the medical history, questionnaire response, results of all tests, and the physician's recommendation;

(c) A copy of the physician's written opinion;

(d) Any employee medical complaints related to exposure to cotton dust;

(e) A copy of this standard and its appendices, except that the employer may keep one copy of the standard and the appendices for all employees, provided that he references the standard and appendices in the medical surveillance record of each employee; and

(f) A copy of the information provided to the physician as required by paragraph (h)(4) of this section.

(iii) The employer shall maintain this record for at least 20 years.

(3) Availability.

(i) The employer shall make all records required to be maintained by paragraph (k) of this section available to the Assistant Secretary and the Director for examination and copying.

(ii) Employee exposure measurement records and employee medical records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20(a)-(e) and (g)-(i).

(4) Transfer of records.

(i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (k) of this section.

(ii) Whenever the employer ceases to do business, and there is no successor employer to receive and retain the records for the prescribed period, these records shall be transmitted to the Director.

(iii) At the expiration of the retention period for the records required to be maintained by this section, the employer shall notify the Director at least 3 months prior to the disposal of such records and shall transmit those records to the Director if the Director requests them within that period.

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

(l) Observation of monitoring.

(1) The employer shall provide affected employees or their designated representatives an op-

portunity to observe any measuring or monitoring of employee exposure to cotton dust conducted pursuant to paragraph (d) of this section.

(2) Whenever observation of the measuring or monitoring of employee exposure to cotton dust requires entry into an area where the use of personal protective equipment is required, the employer shall provide the observer with and assure the use of such equipment and shall require the observer to comply with all other applicable safety and health procedures.

(3) Without interfering with the measurement, observers shall be entitled to:

(i) An explanation of the measurement procedures;

(ii) An opportunity to observe all steps related to the measurement of airborne concentrations of cotton dust performed at the place of exposure; and

(iii) An opportunity to record the results obtained.

(m) Effective date.

(1) **General.** This section is effective March 27, 1980, except as otherwise provided below.

(2) **Startup dates.**

(i) **Initial monitoring.** The initial monitoring required by paragraph (d)(2) of this section shall be completed as soon as possible but no later than March 27, 1980.

(ii) **Methods of compliance: engineering and work practice controls.**

(a) The engineering and work practice controls required by paragraph (e) of this section shall be implemented no later than March 27, 1984 except as set forth in paragraph (m)(2)(ii)(b) of this section.

(b) The engineering and work practice controls required by paragraph (e) of this section shall be implemented no later than March 27, 1986, for ring spinning operations (including only ring spinning and winding, twisting, spooling, beaming and warping following ring spinning), where the operations meet the following criteria:

(1) The weight of the yarn being run is 100 percent cotton and the average yarn count by weight is 18 or below;

(2) The average weight of the yarn run is 80 percent or more cotton and the average yarn count by weight is 16 or below; or

(3) The average weight of the yarn being run is 50 percent or more cotton and the average yarn count by weight is 14 or below.

(c) When the provisions of paragraph (m)(2)(ii)(B) of this section are being relied upon, the following definitions shall apply:

(1) The average cotton content shall be determined by dividing the total weight of cotton in the yarns being run by the total weight of all the yarns being run in the relevant work area.

(2) The average yarn count shall be determined by multiplying the yarn count times the pounds of each particular yarn being run to get the "total hank" for each of the yarns being run in the relevant area. The "total hank" values for all of the yarns being run should then be summed and divided by the total pounds of yarn being run, to produce the average yarn count number for all the yarns being run in the relevant work area.

(d) Where the provisions of paragraph (m)(2)(ii)(b) of this section are being relied upon, the employer shall update the employer's compliance plan no later than February 13, 1986 to indicate the steps being taken to reduce cotton dust levels to 200 $\mu g/m^3$ through the use of engineering and work practice controls by March 27, 1986.

(e) Where the provisions of paragraph (m)(2)(ii)(b) of the section are being relied upon, the employer shall maintain airborne concentrations of cotton dust below 1000 $\mu g/$ MG53 mean concentration averaged over an eight-hour period measured by a vertical elutriator or a method of equivalent accuracy and precision with engineering and work practice controls and shall maintain the permissible exposure limit specified by paragraph (c)(1)(i) of this section with any combination of engineering controls, work practice controls and respirators.

(iii) Compliance program. The compliance program required by paragraph (e)(3) of this section shall be established no later than March 27, 1981.

(iv) Respirators. The respirators required by paragraph (f) of this section shall be provided no later than April 27, 1980.

(v) Work practices. The work practices required by paragraph (g) of this section shall be implemented no later than June 27, 1980.

(vi) Medical surveillance. The medical surveillance required by paragraph (h) of this section shall be completed no later than March 27, 1981 for the textile industry and no later than June 13, 1986 for the cotton seed processing and waste processing industry.

(vii) Employee education and training. The initial education and training required by paragraph (i) of this section shall be completed as soon as possible but no later than June 27, 1980.

(3) Amendments. The amendments to this section published on December 13, 1985 become effective on February 11, 1986. If the amendments are not in effect because of stays of enforcement or judicial decisions, the provisions published in 29 CFR Parts 1900 to 1910, received as of July 1, 1985 are effective.

(n) Washed Cotton.

(1) Exemptions. Cotton, after it has been washed by the processes described in this paragraph, is exempt from all or parts of this section as specified if the requirements of this paragraph are met.

(2) Initial requirements.

(i) In order for an employer to qualify as exempt or partially exempt from this standard for operations using washed cotton, the employer must demonstrate that the cotton was washed in a facility which is open to inspection by the Assistant Secretary and the employer must provide sufficient accurate documentary evidence to demonstrate that the washing methods utilized meet the requirements of this paragraph.

(ii) An employer who handles or processes cotton which has been washed in a facility not under the employer's control and claims an exemption or partial exemption under this paragraph, must obtain from the cotton washer and make available at the worksite, to the Assistant Secretary, to any affected employee, or to their designated representative the following:

(a) A certification by the washer of the cotton of the grade of cotton, the type of washing process, and that the batch meets the requirements of this paragraph:

(b) Sufficient accurate documentation by the washer of the cotton grades and washing process; and

(c) An authorization by the washer that the Assistant Secretary or the Director may inspect the washer's washing facilities and documentation of the process.

(3) Medical and dyed cotton. Medical grade (USP) cotton, cotton that has been scoured, bleached and dyed, and mercerized yarn shall be exempt from all provisions of this standard.

(4) Higher grade washed cotton. The handling or processing of cotton classes as "low middling light spotted or better" which has been washed:

(i) On a continuous batt system or a rayon rinse system;

(ii) With water;

(iii) At a temperature of no less than 60° C;

(iv) With a water-to-fiber ratio of no less than 40:1; and

(v) With bacterial levels in the wash water controlled to limit bacterial contamination of the cotton shall be exempt from all provisions of the standard except the requirements of paragraphs (h) Medical Surveillance, (k)(2)-(4) Recordkeeping-Medical Records, and Appendices B, C, and D of this section.

(5) Lower grade washed cotton. The handling and processing of cotton of grades lower than "low middling light spotted," that has been washed as specified in paragraph (n)(4) of this section and has also been bleached, shall be exempt from all provisions of the standard except the requirements of paragraphs (c)(1)(ii) Permissible Exposure Limit, (d) Exposure Monitoring, (h) Medical Surveillance, (k) Recordkeeping, and Appendices B, C and D of this section.

(6) Mixed grades of washed cotton. If more than one grade of washed cotton is being handled or processed together, the requirements of the grade with the most stringent exposure limit, medical and monitoring requirements shall be followed.

(o) Appendices.

(1) Appendices B, C, and D of this section are incorporated as part of this section and the contents of these appendices are mandatory.

(2) Appendix A of this section contains information which is not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

(3) Appendix E of this section is a protocol which may be followed in the validation of alternative measuring devices as equivalent to the vertical elutriator cotton dust sampler. Other protocols may be used if it is demonstrated that they are statistically valid, meet the requirements in paragraph (d)(1)(iii) of this section, and are appropriate for demonstrating equivalency.

APPENDIX A—AIR SAMPLING AND ANALYTICAL PROCEDURES FOR DETERMINING CONCENTRATIONS OF COTTON DUST

I. SAMPLING LOCATIONS

The sampling procedures must be designed so that samples of the actual dust concentrations are collected accurately and consistently and reflect the concentrations of dust at the place and time of sampling. Sufficient number of 6-hour area samples in each distinct work area of the plant should be collected at locations which provide representative samples of air to which the worker is exposed. In order to avoid filter overloading, sampling time may be shortened when sampling in dusty areas. Samples in each work area should be gathered simultaneously or sequentially during a normal operating period. The daily time-weighted average (TWA) exposure of each worker can then be determined by using the following formula:

$$\frac{\text{Summation of hours spent in each location and the dust concentration in that location.}}{\text{Total hours exposed}}$$

A time-weighted average concentration should be computed for each worker and properly logged and maintained on file for review.

II. SAMPLING EQUIPMENT

(a) Sampler. The instrument selected for monitoring is the Lumsden-Lynch vertical elutriator. It should operate at a flow rate of 7.4±0.2 liters/minute.

The samplers should be cleaned prior to sampling. The pumps should be monitored during sampling.

(b) Filter Holder. A three-piece cassette constructed of polystyrene designed to hold a 37-mm diameter filter should be used. Care must be exercised to insure that an adequate seal exists between elements of the cassette.

(c) Filers and Support Pads. The membrane filters used should be polyvinyl chloride with a 5-um pore size and 37-mm diameter. A support pad, commonly called a backup pad, should be used under the filter membrane in the field monitor cassette.

(d) Balance. A balance sensitive to 10 micrograms should be used.

(e) Monitoring equipment for use in Class III hazardous locations must be approved for use in such locations, in accordance with the requirements of the OSHA electrical standards in Subpart S of Part 1910.

[45 F.R. 67340, October 10, 1980.]

III. INSTRUMENT CALIBRATION PROCEDURE

Samplers shall be calibrated when first received from the factory, after repair, and after receiving any abuse. The samplers should be calibrated in the laboratory both before they are used in the field and after they have been used to collect a large number of field samples. The primary standard, such as a spirometer or other standard calibrating instruments such as a wet test meter or a large bubble meter or dry gas meter, should be used. Instructions for calibration with the wet test meter follow. If another calibration device is selected, equivalent procedures should be used:

(a) Level wet test meter. Check the water level which should just touch the calibration point at the left side of the meter. If water level is low, add water 1-2° F. warmer than room temperature of till point. Run the meter for 30 minutes before calibration;

(b) Place the polyvinyl chloride membrane filter in the filter cassette;

(c) Assemble the calibration sampling train;

(d) Connect the wet test meter to the train.

The pointer on the meter should run clockwise and a pressure drop of not more than 1.0 inch of water indicated. If the pressure drop is greater than 1.0, disconnect and check the system;

(e) Operate the system for ten minutes before starting the calibration;

(f) Check the vacuum gauge on the pump to insure that the pressure drop across the orifice exceeds 17 inches of mercury;

(g) Record the following on calibration data sheets:

(1) Wet test meter reading, start and finish;

(2) Elapsed time, start and finish (at least two minutes);

(3) Pressure drop at manometer;

(4) Air temperature;

(5) Barometric pressure; and

(6) Limiting orifice number;

(h) Calculate the flow rate and compare against the flow of 7.4±0.2 liters/minute. If flow is between these limits, perform calibration again, average results, and record orifice number and flow rate. If flow is not within these limits, discard or modify orifice and repeat procedure;

(i) Record the name of the person performing the calibration, the date, serial number of the wet test meter, and the number of the critical orifices being calibrated.

IV. SAMPLING PROCEDURE

(a) Sampling data sheets should include a log of:

(1) The date of the sample collection;

(2) The time of sampling;

(3) The location of the sampler;

(4) The sampler serial number;

(5) The cassette number;

(6) The time of starting and stopping the sampling and the duration of sampling;

(7) The weight of the filter before and after sampling;

(8) The weight of dust collected (corrected for controls);

(9) The dust concentration measured;

(10) Other pertinent information; and

(11) Name of person taking sample

(b) Assembly of filter cassette should be as follows:

(1) Loosely assemble 3-piece cassette;

(2) Number cassette;

(3) Place absorbant pad in cassette;

(4) Weigh filter to an accuracy of 10 μg;

(5) Place filter in cassette;

(6) Record weight of filter in log, using cassette number for identification;

(7) Fully assemble cassette, using pressure to force parts tightly together;

(8) Install plugs top and bottom;

(9) Put shrink band on cassette, covering joint between center and bottom parts of cassette; and

(10) Set cassette aside until shrink band dries thoroughly.

(c) Sampling collection should be performed as follows:

(1) Clean lint out of the motor and elutriator;

(2) Install vertical elutriator in sampling locations specified above with inlet 4¼ to 5¼ feet from floor (breathing zone height);

(3) Remove top section of cassette;

(4) Install cassette to ferrule of elutriator.

(5) Tape cassette to ferrule with masking tape or similar material for air tight seal.

(6) Remove bottom plug of cassette and attach hose containing critical orifice;

(7) Start elutriator pump and check to see if gauge reads above 17 in. of Hg vacuum;

(8) Record starting time, cassette number, and sampler number;

(9) At end of sampling period stop pump and record time; and

(10) Controls with each batch of samples collected, two additional filter cassettes should be subjected to exactly the

same handling as the samples, except that they are not opened. These control filters should be weighed in the same manner as the sample filters.

Any difference in weight in the control filters would indicate that the procedure for handling sample filters may not be adequate and should be evaluated to ascertain the cause of the difference, whether and what necessary corrections must be made, and whether additional samples must be collected.

(d) Shipping. The cassette with samples should be collected, along with the appropriate number of blanks, and shipped to the analytical laboratory in a suitable container to prevent damage in transit.

(e) Weighing of the sample should be achieved as follows:

(1) Remove shrink band;

(2) Remove top and middle sections of cassette and botton plug;

(3) Remove filter from cassette and weigh to an accuracy of 10 μg; and

(4) Record weight in log against original weight

(f) Calculation of volume of air sampled should be determined as follows:

(1) From starting and stopping times of sampling period, determine length of time in minutes of sampling period; and

(2) Multiply sampling time in minutes by flow rate of critical orifice in liters per minute and divide by 1000 to find air quantity in cubic meters.

(g) Calculation of Dust Concentrations should be made as follows:

(1) Substract weight of clean filter from dirty filter and apply control correction to find actual weight of sample. Record this weight (in μg) in log; and

(2) Divide mass of sample in μg by air volume in cubic meters to find dust concentration in $\mu g/m$. Record in log.

APPENDIX B-I

RESPIRATORY QUESTIONNAIRE

A. IDENTIFICATION DATA

PLANT________________ SOCIAL SECURITY NO.________________

DAY MONTH (figures) YEAR (last 2 digits)

NAME________________ (Surname) DATE OF INTERVIEW________________

________________ (First Names) DATE OF BIRTH________________

ADDRESS________________ AGE______(8,9) SEX M______ F______(10)

RACE W N IND. OTHER (11)

INTERVIEWER: 1 2 3 4 5 6 7 8 (12)

WORK SHIFT: 1st______ 2nd______ 3rd______(13) STANDING HEIGHT______(14,15)

PRESENT WORK AREA WEIGHT______(16,18)

If working in more than one specified work area, X area where most of the work shift is spent. If "other," but spending 25% of the work shift in one of the specified work areas, classify in that work area. If carding department employee, check area within that department where most of the work shift is spent (if in doubt, check "throughout"). For work areas such as spinning and weaving where many work rooms may be involved, be sure to check the specific work room to which employee is assigned — if he works in more than one work room within a department classify as 7 (all) for that department.

	Workroom Number	(19) Open	(20) Pick	Area	(21) Card #1	(22) #2	(23) Spin	(24) Wind	(25) Twist	(26) Spool	(27) Warp	(28) Slash	(29) Weave	(30) Other
AT RISK (cotton & cotton blend)	1			Cards										
	2			Draw										
	3			Comb										
	4			Rove										
	5			Thru Out										
	6													
	7 (all)													
Control (synthetic & wool)	8													
Ex-Worker (cotton)	9													

b. The following guidelines are recommended by NIOSH for the evaluation and management of workers exposed to cotton dust. It is important to note that employees who show reductions in FEV_1/FVC ratio below .75 or drops in Monday FEV_1 of 5 percent or greater on their initial screening exam, should be re-evaluated within a month of the first exam. Those who show consistent decrease in lung function, as shown on the following table, should be managed as recommended.

IV. QUALIFICATIONS OF PERSONNEL ADMINISTERING THE TEST

Technicians who perform pulmonary function testing should have the basic knowledge required to produce meaningful results. Training consisting of approximately 16 hours of formal instruction should cover the following areas.

a. Basic physiology of the forced vital capacity maneuver and the determinants of airflow limitation with emphasis on the relation to reproducibility of results.

b. Instrumentation requirements including calibration procedures, sources of error and their correction.

c. Performance of the testing including subject coaching, recognition of improperly performed maneuvers and corrective actions.

d. Data quality with emphasis on reproducibility.

e. Actual use of the equipment under supervised conditions.

f. Measurement of tracings and calculations of results.

[43 F.R. 27394, June 23, 1978.]

[corrected at 43 F.R. 28473, June 30, 1978, and 43 F.R. 35032, August 8, 1978.]

APPENDIX E—VERTICAL ELUTRIATOR EQUIVALENCY PROTOCOL

a. Samples to be taken. In order to ascertain equivalency, it is necessary to collect a total of 100 samples from at least 10 sites in a mill. That is, there should be 10 replicate readings at each of 10 sites. The sites should represent dust levels which vary over the allowable range of 0.5 to 2 times the permissible exposure limit. Each sample requires the use of two vertical elutriators (VE's) and at least one but not more than two alternative devices (AD's). Thus, the end result is 200 VE readings and either 100 or 200 AD readings. The 2 VE readings and the 1 or 2 AD readings at each time and site must be made simultaneously. That is, the two VE's and one or two AD's must be arranged together in such a way that they are measuring essentially the same dual levels.

b. Data averaging. The two VE readings taken at each site are then averaged. These averages are to be used as the 100 VE readings. If two alternate devices were used, their test results are also averaged. Thus, after this step is accomplished, there will be 100 VE readings and 100 AD readings.

c. Differences For each of the 100 sets of measurements (VE and AD) the difference is obtained as the average VE reading minus the AD reading. Call these differences, D_i. Thus, we have.

$$D_i = VE_i - AD_i,\ i = 1,2,\ldots,100 \qquad (1)$$

Next we compute the arithmetic mean and standard deviations of the differences, using equations (2) and (3), respectively.

$$\overline{X_D} = \frac{1}{N} \sum_{i=1}^{N} D_i \qquad (2)$$

$$S_D = \sqrt{\frac{\Sigma D_i^2 - \frac{(\Sigma D_i)^2}{N}}{N-1}} \qquad (3)$$

where N equals the number of differences (100 in this case). $\bar{X}_D$ is the arithmetic mean and S_D is the standard deviation.

We next calculate the critical value as $T = KS_D + |\bar{X}_D|$ where $K = 1.87$, based on 100 samples.

d. Equivalency test. The next step is to obtain the average of the 100 VE readings. This is obtained by equation (4).

$$X_{VE} = \frac{1}{N}\left(\sum_{i=1}^{N} VE_i\right) \qquad (4)$$

We next multiply 0.25 by $\bar{X}_{VE}$. If $T < 0.25\ \overline{X_{VE}}$ we can say that the alternate device has passed the equivalency test.

(The information collection requirements contained in the section are under consideration by the Office of Management and Budget. They will not take effect until approved.)

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ment. For claims for cases described in §404.2101(a), a clear explanation or existing documentation which demonstrates how the service contributed to the individual's performance of a continuous 9-month period of SGA must be provided. For claims for cases described in §404.2101(b) or (c), a clear explanation or existing documentation which demonstrates how the service was reasonably expected to motivate or assist the individual to return to or continue in SGA must be provided. If we find in any prepayment validation review, that the scope or content of the information is inadequate, we will request additional information and will withhold payment until adequate information has been provided. The State VR agency or alternate participant shall permit us (including duly authorized representatives) access to, and the right to examine, any records relating to such services and costs. Any review performed under this section will not be considered an audit for purposes of this subpart.

(b) *Purpose.* The primary purpose of these reviews is—

(1) To ensure that the VR services and costs meet the requirements for payment under this subpart;

(2) To assess the validity of our documentation requirements; and

(3) To assess the need for additional validation reviews or additional documentation requirements for any State VR agency or alternate participant to ensure compliance with the requirements under this subpart.

(c) *Determinations.* In any validation review, we will determine whether the VR services and costs meet the requirements for payment and determine the amount of payment. We will notify in writing the State VR agency or alternate participant of our determination. If we find in any postpayment validation review that more or less than the correct amount of payment was made for a claim, we will determine that an overpayment or underpayment has occurred and will notify the State VR agency or alternate participant that we will make the appropriate adjustment.

(d) *Appeals.* If the State VR agency or alternate participant disagrees with our determination under this section, it may appeal that determination in accordance with §404.2127. For purposes of this section, an appeal must be filed within 60 days after receiving the notice of our determination.

[59 FR 11916, Mar. 15, 1994]

§404.2122 Confidentiality of information and records.

The State or alternate participant shall comply with the provisions for confidentiality of information, including the security of systems, and records requirements described in 20 CFR part 401 and pertinent written guidelines (see §404.2123).

§404.2123 Other Federal laws and regulations.

Each State VR agency and alternate participant shall comply with the provisions of other Federal laws and regulations that directly affect its responsibilities in carrying out the vocational rehabilitation function.

§404.2127 Resolution of disputes.

(a) *Disputes on the amount to be paid.* The appropriate SSA official will notify the State VR agency or alternative participant in writing of his or her determination concerning the amount to be paid. If the State VR agency (see §404.2118(b) for alternate participants) disagrees with that determination, the State VR agency may request reconsideration in writing within 60 days after receiving the notice of determination. The Commissioner will make a determination and notify the State VR agency of that decision in writing, usually no later than 45 days from the date of the State VR agency's appeal. The decision by the Commissioner will be final and conclusive upon the State VR agency unless the State VR agency appeals that decision in writing in accordance with 45 CFR part 16 to the Department of Health and Human Services Departmental Grant Appeals Board within 30 days after receiving the Commissioner's decision.

(b) *Disputes on whether there was a continuous period of SGA and whether VR services contributed to a continuous period of SGA.* The rules in paragraph (a) of this section will apply, except that the Commissioner's decision will be final and conclusive. There is no right of appeal to the Grant Appeals Board.

(c) *Disputes on determinations made by the Secretary which affect a disability beneficiary's rights to benefits.* Determinations made by the Secretary which affect an individual's right to benefits (e.g., determinations that disability benefits should be terminated, denied, suspended, continued or begun at a different date than alleged) cannot be appealed by a State VR agency or alternate participant. Because these determinations are an integral part of the disability benefits claims process, they can only be appealed by the beneficiary or applicant whose rights are affected or by his or her authorized representative. However, if an appeal of an unfavorable determination is made by the individual and is successful, the new determination would also apply for purposes of this subpart. While a VR agency or alternate participant cannot appeal a determination made by the Secretary which affects a beneficiary's or applicant's rights, the VR agency can furnish any evidence it may have which would support a revision of a determination.

[48 FR 6293, Feb. 10, 1983, as amended at 55 FR 8456, Mar. 8, 1990]

PART 410—FEDERAL COAL MINE HEALTH AND SAFETY ACT OF 1969, TITLE IV—BLACK LUNG BENEFITS (1969–)

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AUTHORITY: Secs. 3 (g) and (h), 402, 411, 412, 413, 414, 426(a), and 508, 83 Stat. 744; 30 U.S.C. 802 (g) and (h), 902, 921–924, 936(a), and 957. sec. 410.120 also issued under sec. 1106, 53 Stat. 1398, as amended, 42 U.S.C. 1306.

§ 410.101 Introduction.

The regulations in this part 410 (Regulation No. 10 of the Social Security Administration) relate to the provisions of part B (Black Lung Benefits) of title IV of the Federal Coal Mine Health and Safety Act of 1969, as enacted December 30, 1969, as amended by the Black Lung Benefits Act of 1972, and as may hereafter be amended. The regulations in this part are divided into the following subparts according to subject content:

(a) This subpart A contains this introduction, general provisions, and provisions relating to definitions and the use of terms.

(b) Subpart B of this part relates to the requirements for entitlement, duration of entitlement, filing of claims, and evidence.

(c) Subpart C of this part describes the relationship and dependency required for widows, children, parents, brothers, and sisters, and relationship and dependency requirements which affect the benefit amounts of entitled miners and widows.

(d) Subpart D of this part provides standards for determining total disability and death due to pneumoconiosis.

(e) Subpart E of this part relates to payment of benefits, payment periods, benefit rates and their modification, representative payees, and overpayments and underpayments.

(f) Subpart F of this part relates to determinations of disability and other determinations, the procedures for administrative review, finality of decisions, and the representation of parties.

[36 FR 23752, Dec. 14, 1971, as amended at 37 FR 20635, Sept. 30, 1972]

§ 410.110 General definitions and use of terms.

For purposes of this part, except where the context clearly indicates otherwise, the following definitions apply:

(a) *The Act*, means the Federal Coal Mine Health and Safety Act of 1969 (Pub. L. 91–173), enacted December 30, 1969, as amended by the Black Lung Benefits Act of 1972 (Pub. L. 92–303), enacted May 19, 1972, and as may hereafter be amended.

(b) *Benefit* means the black lung benefit provided under part B of title IV of the Act to coal miners, to surviving widows of miners, to the surviving child or children of a miner, or of a widow of a miner, to the surviving dependent parent or parents of a miner, and to the surviving dependent brother(s) or sister(s) of a miner.

(c) *Secretary* means the Secretary of Health, Education, and Welfare.

(d) *Commissioner* means the Commissioner of Social Security.

(e) *Administration* means the Social Security Administration in the Department of Health, Education, and Welfare.

(f) *Appeals Council* means the Appeals Council of the Bureau of Hearings and Appeals in the Social Security Administration or such member or members thereof as may be designated by the Chairman.

(g) *Administrative Law Judge* means an Administrative Law Judge in the Bureau of Hearings and Appeals of the Social Security Administration.

(h) *Coal mine* means an area of land and all structures, facilities, machinery, tools, equipment, shafts, slopes, tunnels, excavations, and other property, real or personal, placed upon, under, or above the surface of such land by any person, used in, or to be used in, or resulting from, the work of extracting in such area bituminous coal, lignite, or anthracite from its natural deposits in the earth by any means or method, and the work of preparing the coal so extracted, and includes custom coal preparation facilities.

(i) *Underground coal mine* means a coal mine in which the earth and other materials which lie above the natural deposit of coal (overburden) is not removed in mining. In addition to the natural deposits of coal in the earth, the underground mine includes all land, buildings and equipment appurtenant thereto.

(j) *Miner* or *coal miner* means any individual who is working or has worked as an employee in a coal mine, performing functions in extracting the coal or preparing the coal so extracted.

(k) *The Nation's coal mines* comprise all coal mines as defined in paragraph (h) of this section located in a State as defined in paragraph (l) of this section.

(l) *State* includes a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Trust Territory of the Pacific Islands, and prior to January 3, 1959, and August 21, 1959, respectively, the Territories of Alaska and Hawaii.

(m) *Employee* means an individual in a legal relationship (between the person for whom he performs services and himself) of employer and employee under the usual common-law rules.

(1) Generally, such relationship exists when the person for whom services are performed has the right to control and direct the individual who performs the services, not only as to the result to be accomplished by the work but also as to the means by which that result is accomplished; that is, an employee is subject to the will and control of the employer not only as to what shall be done but how it shall be done. In this connection, it is not necessary that the employer actually direct or control the manner in which the services are performed; it is sufficient if he has the right to do so. The right to discharge is also an important factor indicating that the person possessing that right is an employer. Other factors characteristic of an employer, but not necessarily present in every case, are the furnishing of tools and the furnishing of a place to work to the individual who performs the services. In general, if an individual is subject to the control or direction of another merely as to the result to be accomplished by the work and not as to the means and methods for accomplishing the result, he is an independent contractor. An individual performing services as an independent contractor is not as to such services an employee under the usual common-law rules.

(2) Whether the relationship of employer and employee exists under the usual common-law rules will in doubtful cases be determined upon an examination of the particular facts of each case.

(n) The *Social Security Act* means the Social Security Act (49 Stat. 620) as amended from time to time.

probable does not in and of itself preclude a finding that the parties were "living with" one another or were "member[s] of the same household" etc. at the time of death.

(d) *Absences other than temporary.* In situations other than those described in paragraphs (b) and (c) of this section, the absence shall not be considered temporary, and the parties may not be found to be "living with" one another or to be "member[s] of the same household" etc. A finding of temporary absence would not be justified where one of the parties was committed to a penal institution for life or for a period exceeding the reasonable life expectancy of either, or was under a sentence of death; or where the parties had ceased to live in the same place of abode because of marital or family difficulties and had not resumed living together before death.

(e) *Relevant period of time.* (1) The determination as to whether a widow had been "living with" her husband shall be based upon the facts and circumstances as of the time of death of the miner.

(2) The determination as to whether a wife is a "member of the same household" as her husband shall be based upon the facts and circumstances with respect to the period or periods of time as to which the issue of membership in the same household is material. (See §410.510(c).)

(3) The determination as to whether a parent, brother, or sister was "living in the miner's household" shall take account only of the 1-year period immediately prior to the miner's death. (See §410.380.)

[37 FR 20640, Sept. 30, 1972]

§410.394 [Reserved]

§410.395 Contributions and support.

(a) *Support* defined. The term *support* includes food, shelter, clothing, ordinary medical expenses, and other ordinary and customary items for the maintenance of the person supported.

(b) *Contributions* defined. The term *contributions* refers to contributions actually provided by the contributor from his own property, or the use thereof, or by the use of his own credit.

(c) *Regular contributions* and *substantial contributions* defined. The terms *regular contributions* and *substantial contributions* mean contributions that are customary and sufficient to constitute a material factor in the cost of the individual's support.

(d) *Contributions and community property.* When a wife receives, and uses for her support, income from her services or property and such income, under applicable State law, is the community property of herself and the miner, no part of such income is a *contribution* by the miner to his wife's support regardless of any legal interest the miner may have therein. However, when a wife receives, and uses for her support, income from the services and the property of the miner and, under applicable State law, such income is community property, all of such income is considered to be a contribution by the miner to his wife's support.

(e) *Court order for support* defined. References to support orders in §§410.330 (f)(1), 410.350(c), and 410.360(b) mean any court order, judgment, or decree of a court of competent jurisdiction which requires regular contributions that are a material factor in the cost of the individual's support and which is in effect at the applicable time. If such contributions are required by a court order, this condition is met whether or not the contributions were actually made.

(f) *Written agreement* defined. The term *written agreement* in the phrase *substantial contributions * * * pursuant to a written agreement* (see §§410.351 (b) and 410.361(b)) means an agreement signed by the miner providing for substantial contributions by him for the individual's support. It must be in effect at the applicable time but it need not be legally enforceable.

(g) *One-half support* defined. The term *one-half support* means that the miner made regular contributions, in cash or in kind, to the support of a divorced wife (see §410.351(a)), or of a surviving divorced wife (see §410.361 (a)), at the specified time or for the specified period, and that the amount of such contributions equaled or exceeded one-half the total cost of such individual's support at such time or during such period.

(h) *Totally dependent for support* defined. The term *totally dependent on the miner for support* as used in §410.380(b), means that such miner made regular contributions to the support of his parent, brother, or sister, as the case may be, and that the amount of such contributions at least equaled the total cost of such individual's support.

[37 FR 20641, Sept. 30, 1972]

Subpart D—Total Disability or Death Due to Pneumoconiosis

AUTHORITY: Secs. 401-426, 83 Stat. 792, as amended, 86 Stat. 150; 30 U.S.C. 901 *et seq.*

SOURCE: 37 FR 20641, Sept. 30, 1972, unless otherwise noted.

§410.401 Scope of subpart D.

(a) *General.* This subpart establishes the standards for determining whether a coal miner is totally disabled due to pneumoconiosis, whether he was totally disabled due to pneumoconiosis at the time of his death, or whether his death was due to pneumoconiosis.

(b) *Pneumoconiosis* defined. *Pneumoconiosis* means:

(1) A chronic dust disease of the lung arising out of employment in the Nation's coal mines, and includes coal workers' pneumoconiosis, anthracosilicosis, anthracosis, anthrosilicosis, massive pulmonary fibrosis, progressive massive fibrosis, silicosis, or silicotuberculosis, arising out of such employment. For purposes of this subpart, the term also includes the following conditions that may be the basis for application of the statutory presumption of disability or death due to pneumoconiosis under the circumstances prescribed in section 411 (c) of the Act;

(2) Any other chronic respiratory or pulmonary impairment when the conditions are met for the application of the presumption described in §410.414(b) or §410.454(b), and

(3) Any respirable disease when the conditions are met for the application of the presumption described in §410.462. The provisions for determining that a miner is or was totally disabled due to pneumoconiosis or its sequelae are included in §§410.410 through 410.430 and in the Appendix following this subpart D. The provisions for determining that a miner's death was due to pneumoconiosis are included in §§410.450 through 410.462. Certain related provisions of general application are included in §§410.470 through 410.476.

(c) *Relation to the Social Security Act.* Section 402(f) of the Act, as amended, 30 U.S.C. 902(f), provides that regulations defining total disability "shall not provide more restrictive criteria than those applicable under section 223(d) of the Social Security Act." Section 413(b) of the Act, 30 U.S.C. 923(b), also provides, in pertinent part, that in "carrying out the provisions of this part [that is, part B of title IV of the Act], the Secretary [of Health, Education, and Welfare] shall to the maximum extent feasible (and consistent with the provisions of this part) utilize the * * * procedures he uses in determining entitlement to disability insurance benefits under section 223 of the Social Security Act * * *."

§410.410 Total disability due to pneumoconiosis, including statutory presumption.

(a) Benefits are provided under the Act to coal miners "who are totally disabled due to pneumoconiosis arising out of employment in one or more of the Nation's coal mines," and to the eligible survivors of miners who are determined to have been totally disabled due to pneumoconiosis at the time of their death. (For benefits to the eligible survivors of miners whose deaths are determined to have been due to pneumoconiosis, see §410.450.)

(b) To establish entitlement to benefits on the basis of a coal miner's total disability due to pneumoconiosis, a claimant must submit the evidence necessary to establish: (1) That he is a coal miner, that he is totally disabled due to pneumoconiosis, and that his pneumoconiosis arose out of employment in the Nation's coal mines; or (2) that the deceased individual was a miner, that he was totally disabled due to pneumoconiosis at the time of his death, and that his pneumoconiosis arose out of employment in the Nation's coal mines.

(c) Total disability is defined in §410.412; the basic provision on determining the existence of pneumoconiosis is in §410.414; and the requirement that the pneumoconiosis must have arisen out of coal mine employment is in §410.416. The statutory presumptions with respect to the burden of proving the foregoing are in §§410.414(b), 410.416(a), and 410.418, and the provision for determining the existence of total disability when the presumption in §410.418 does not apply is included in §410.422.

§410.412 "Total disability" defined.

(a) A miner shall be considered totally disabled due to pneumoconiosis if:

(1) His pneumoconiosis prevents him from engaging in gainful work in the immediate area of his residence requiring the skills and abilities comparable to those of any work in a mine or mines in which he previously engaged with some regularity and over a substantial period of time (that is, "comparable and gainful work"; see §§410.424 through 410.426); and

(2) His impairment can be expected to result in death, or has lasted or can be expected to last for a continuous period of not less than 12 months.

(b) A miner shall be considered to have been totally disabled due to pneumoconiosis at the time of his death, if at the time of his death:

(1) His pneumoconiosis prevented him from engaging in gainful work in the immediate area of his residence requiring the skills and abilities comparable to those of any work in a mine or mines in which he previously engaged with some regularity and over a substantial period of time (that is, "comparable and gainful work"; see §§410.424 through 410.426); and

(2) His impairment was expected to result in death, or it lasted or was expected to last for a continuous period of not less than 12 months.

§410.414 Determining the existence of pneumoconiosis, including statutory presumption.

(a) *General.* A finding of the existence of pneumoconiosis as defined in §410.110(o)(1) may be made under the provisions of §410.428 by:

(1) Chest roentgenogram (X-ray); or

(2) Biopsy; or

(3) Autopsy.

(b) *Presumption relating to respiratory or pulmonary impairment.* (1) Even though the existence of pneumoconiosis is not established as provided in paragraph (a) of this section, if other evidence demonstrates the existence of a totally disabling chronic respiratory or pulmonary impairment (see §§410.412, 410.422, and 410.426), it may be presumed, in the absence of evidence to the contrary (see paragraph (b)(2) of this section), that a miner is totally disabled due to pneumoconiosis, or that a miner was totally disabled due to pneumoconiosis at the time of his death.

(2) This presumption may be rebutted only if it is established that the miner does not, or did not, have pneumoconiosis, or that his respiratory or pulmonary impairment did not arise out of, or in connection with, employment in a coal mine.

(3) The provisions of this paragraph shall apply where a miner was employed for 15 or more years in one or more of the Nation's underground coal mines; in one or more of the Nation's other coal mines where the environmental conditions were substantially similar to those in an underground coal mine; or in any combination of both.

(4) However, where the evidence shows a work history reflecting many years of such coal mine employment (although less than 15), as well as a severe lung impairment, such evidence may be considered, in the exercise of sound judgment, to establish entitlement in such case, provided that a mere showing of a respiratory or pulmonary impairment shall not be sufficient to establish such entitlement.

(c) *Other relevant evidence.* Even though the existence of pneumoconiosis is not established as provided in paragraph (a) or (b) of this section, a finding of total disability due to pneumoconiosis may be made if other relevant evidence establishes the existence of a totally disabling chronic respiratory or pulmonary impairment, and that such impairment arose out of employment in a coal mine. As used in this paragraph, the term *other relevant evidence* includes medical tests such as blood gas studies, electrocardiogram, pulmonary function studies, or physical performance tests, and any medical history, evidence submitted by the miner's physician, his spouse's affidavits, and in the case of a deceased miner, other appropriate affidavits of persons with knowledge of the individual's physical condition, and other supportive materials. In any event, no claim for benefits under part B of title IV of the Act shall be denied solely on the basis of a negative chest roentgenogram (X-ray).

§410.416 Determining origin of pneumoconiosis, including statutory presumption.

(a) If a miner was employed for 10 or more years in the Nation's coal mines, and is suffering or suffered from pneumoconiosis, it will be presumed, in the absence of persuasive evidence to the contrary, that the pneumoconiosis arose out of such employment.

(b) In any other case, a miner who is suffering or suffered from pneumoconiosis, must submit the evidence necessary to establish that the pneumoconiosis arose out of employment in the Nation's coal mines. (See §410.110(h), (i), (j), (k), (l), and (m).)

§410.418 Irrebuttable presumption of total disability due to pneumoconiosis.

There is an irrebuttable presumption that a miner is totally disabled due to pneumoconiosis, or that a miner was totally disabled due to pneumoconiosis at the time of his death, if he is suffering or suffered from a chronic dust disease of the lung which:

(a) When diagnosed by chest roentgenogram (X-ray), yields one or more large opacities (greater than 1 centimeter in diameter) and would be classified in Category A, B, or C (that is, as *complicated pneumoconiosis*), in:

(1) The ILO-U/C International Classification of Radiographs of Pneumoconioses, 1971, or

(2) The International Classification of the Radiographs of the Pneumoconioses of the International Labour Office, Extended Classification (1968) (which may be referred to as the "ILO Classification (1968)"), or

(3) The Classification of the Pneumoconiosis of the Union Internationale Contra Cancer/Cincinnati (1968) (which may be referred to as the "UICC/Cincinnati (1968) Classification"); or

(b) When diagnosed by biopsy or autopsy, yields massive lesions in the lung. The report of biopsy or autopsy will be accepted as evidence of complicated pneumoconiosis if the histological findings show simple pneumoconiosis and progressive massive fibrosis; or

(c) When established by diagnoses by means other than those specified in paragraphs (a) and (b) of this section, would be a condition which could reasonably be expected to yield the results described in paragraph (a) or (b) of this section had diagnoses been made as therein prescribed; *Provided, however,* That any diagnoses made under this paragraph shall accord with generally accepted medical procedures for diagnosing pneumoconiosis.

§410.422 Determining total disability: General criteria.

(a) A determination of total disability due to pneumoconiosis is made in accordance with this section when a miner cannot be presumed to be totally disabled due to pneumoconiosis (or to have been totally disabled due to pneumoconiosis at the time of his death), under the provisions of §410.418. In addition, when a miner has (or had) a chronic respiratory or pulmonary impairment, a determination of whether or not such impairment is (or was) totally disabling is also made in accordance with this section for purposes of §410.414(b).

(b) A determination of total disability may not be made for purposes of this part unless pneumoconiosis is (or is presumed to be) the impairment involved.

(c) Whether or not the pneumoconiosis in a particular case renders (or rendered) a miner totally disabled, as defined in §410.412, is determined from all the facts of that case. Primary consideration is given to the medical severity of the individual's pneumoconiosis (see §410.424). Consideration is also given to such other factors as the individual's age, education, and work experience (see §410.426).

§410.424 Determining total disability: Medical criteria only.

(a) Medical considerations alone shall justify a finding that a miner is (or was) totally disabled where his impairment is one that meets (or met) the duration requirement in §410.412(a)(2) or §410.412(b)(2), and is listed in the Appendix to this subpart, or if his impairment is medically the equivalent of a listed impairment. However, medical considerations alone shall not justify a finding that an individual is (or was) totally disabled if other evidence rebuts such a finding, e.g., the individual is (or was) engaged in comparable and gainful work (see §410.412).

(b) An individual's impairment shall be determined to be medically the equivalent of an impairment listed in the appendix to this subpart only if the medical findings with respect thereto are at least equivalent in severity and duration to the listed findings of the listed impairment. Any decision as to whether an individual's impairment is medically the equivalent of an impairment listed in the Appendix to this subpart, shall be based on medically accepted clinical and laboratory diagnostic techniques, including a medical judgment furnished by one or more physicians designated by the Administration, relative to the question of medical equivalence.

§410.426 Determining total disability: Age, education, and work experience criteria.

(a) Pneumoconiosis which constitutes neither an impairment listed in the appendix to this subpart (see §410.424), nor the medical equivalent thereof, shall nevertheless be found totally disabling if because of the severity of such impairment, the miner is (or was) not only unable to do his previous coal mine work, but also cannot (or could not), considering his age, his education, and work experience, engage in any other kind of comparable and gainful work (see §410.412(a)(1)) available to him in the immediate area of his residence. A miner shall be determined to be under a disability only if his pneumoconiosis is (or was) the primary reason for his inability to engage in such comparable and gainful work. Medical impairments other than pneumoconiosis may not be considered.

The following criteria recognize that an impairment in the transfer of oxygen from the lung alveoli to cellular level can exist in an individual even though his chest roentgenogram (X-ray) or ventilatory function tests are normal.

(b) Subject to the limitations in paragraph (a) of this section, pneumoconiosis shall be found disabling if it is established that the miner has (or had) a respiratory impairment because of pneumoconiosis demonstrated on the basis of a ventilatory study in which the maximum voluntary ventilation (MVV) or maximum breathing capacity (MBC), and 1-second forced expiratory volume (FEV_1), are equal to or less than the values specified in the following table or by a medically equivalent test:

Height (inches)	MVV (MBC) equal to or less than L/Min.	FEV_1 equal to or less than L
57 or less	52	1.4
58	53	1.4
59	54	1.4
60	55	1.5
61	56	1.5
62	57	1.5
63	58	1.5
64	59	1.6
65	60	1.6
66	61	1.6
67	62	1.7
68	63	1.7
69	64	1.8
70	65	1.8
71	66	1.8
72	67	1.9
73 or more	68	1.9

(c) Where the values specified in paragraph (b) of this section are not met, pneumoconiosis may nevertheless be found disabling if a physical performance test establishes a chronic respiratory or pulmonary impairment which is medically the equivalent of the values specified in the table in paragraph (b) of this section. Any decision with respect to such medical equivalence shall be based on medically accepted clinical and laboratory diagnostic techniques including a medical judgment furnished by one or more physicians designated by the Administration.

(d) Where a ventilatory study and/or a physical performance test is medically contraindicated, or cannot be obtained, or where evidence obtained as a result of such tests does not establish that the miner is totally disabled, pneumoconiosis may nevertheless be found totally disabling if other relevant evidence (see §410.414(c)) establishes that the miner has (or had) a chronic respiratory or pulmonary impairment, the severity of which prevents (or prevented) him not only from doing his previous coal mine work, but also, considering his age, his education, and work experience, prevents (or prevented) him from engaging in comparable and gainful work.

(e) When used in this section, the term *age* refers to chronological age and the extent to which it affects the miner's capacity to engage in comparable and gainful work.

(f) When used in this section, the term *education* is used in the following sense: Education and training are factors in determining the employment capacity of a miner. Lack of formal schooling, however, is not necessarily proof that a miner is an uneducated person. The kinds of responsibilities with which he was charged when working may indicate ability to do more than unskilled work even though his formal education has been limited.

§410.428 X-ray, biopsy, and autopsy evidence of pneumoconiosis.

(a) A finding of the existence of pneumoconiosis as defined in §410.110(o)(1) may be made under the provisions of §410.414(a) if:

(1) A chest roentgenogram (X-ray) establishes the existence of pneumoconiosis classified as Category 1, 2, 3, A, B, or C according to:

(i) The ILO–U/C International Classification of Radiographs of Pneumoconioses, 1971; or

(ii) The International Classification of Radiographs of the Pneumoconioses of the International Labour Office, Extended Classification (1968); or

(iii) The Classification of the Pneumoconioses of the Union Internationale Contra Cancer/Cincinnati (1968).

A chest roentgenogram (X-ray) classified as Category Z under the ILO Classification (1958) or Short Form (1968) will be reclassified as Category 0 or Category 1 and only the latter accepted as evidence of pneumoconiosis. A chest roentgenogram (X-ray) classified under any of the foregoing classifications as Category 0, including subcategories o/–, o/o, or o/1 under the UICC/Cincinnati (1968) Classification, is not accepted as evidence of pneumoconiosis; or

(2) An autopsy shows the existence of pneumoconiosis, or

(3) A biopsy (other than a needle biopsy) shows the existence of pneumoconiosis. Such biopsy would not be expected to be performed for the sole purpose of diagnosing pneumoconiosis. Where a biopsy is performed for other purposes, however (e.g., in connection with a lung resection), the report thereof will be considered in determining the existence of pneumoconiosis.

(b) The roentgenogram shall be of suitable quality for proper classification of the pneumoconioses and conform to accepted medical standards. It should represent a posterior-anterior view of the chest, and such other views as the Administration may require, taken at a preferred distance of 6 feet (a minimum of 5 feet is required) between the focal point and the film on a 14 × 17 inch or 14 × 14 inch X-ray film. Additional films or views should be obtained, if necessary, to provide a suitable roentgenogram (X-ray) for proper classification purposes.

(c) A report of autopsy or biopsy shall include a detailed gross (macroscopic) and microscopic description of the lungs or visualized portion of a lung. If an operative procedure has been performed to obtain a portion of a lung, the evidence should include a copy of the operative note and the pathology report of the gross and microscopic examination of the surgical specimen. If any autopsy has been performed, the evidence should include a complete copy of the autopsy report.

§410.430 Ventilatory studies.

Spirometric tests to measure ventilatory function must be expressed in liters or liters per minute. ~~The reported maximum voluntary ventilation (MVV) or maximum breathing capacity (MBC) and 1-second forced expiratory~~

volume (FEV_1) should represent the largest of at least three attempts. The MVV or the MBC reported should represent the observed value and should not be calculated from FEV_1. The three appropriately labeled spirometric tracings, showing distance per second on the abscissa and the distance per liter on the ordinate, must be incorporated in the file. The paper speed to record the FEV_1 should be at least 20 millimeters (mm.) per second. The height of the individual must be recorded. Studies should not be performed during or soon after an acute respiratory illness. If wheezing is present on auscultation of the chest, studies must be performed following administration of nebulized broncho-dilator unless use of the later is contraindicated. A statement shall be made as to the individual's ability to understand the directions, and cooperate in performing the tests. If the tests cannot be completed the reason for such failure should be explained.

§410.432 Cessation of disability.

(a) Where it has been determined that a miner is totally disabled under §410.412, such disability shall be found to have ceased in the month in which his impairment, as established by medical or other relevant evidence, is no longer of such severity as to prevent him from engaging in comparable and gainful work.

(b) Except where a finding is made as specified in paragraph (a) of this section which results in an earlier month of cessation, if a miner is requested to furnish necessary medical or other evidence or to present himself for a necessary medical examination by a date specified in the request or a date extended at the miner's request for good cause, and the miner fails to comply with such request, the disability may be found to have ceased in the month within which the date for compliance falls, unless the Administration determines that there is a good cause for such failure.

(c) Before a determination is made that a miner's disability has ceased, such miner shall be given notice and an opportunity to present evidence including that from medical sources of his own choosing and arguments and contention that his disability has not ceased.

§410.450 Death due to pneumoconiosis, including statutory presumption.

Benefits are provided under the Act to the eligible survivor of a coal miner who was entitled to benefits at the time of his death, or whose death is determined to have been due to pneumoconiosis. (For benefits to the eligible survivors of a miner who is determined to have been totally disabled due to pneumoconiosis at the time of his death, regardless of the cause of death, see §§410.410 through 410.430.) Except as otherwise provided in §§410.454 through 410.462, the claimant must submit the evidence necessary to establish that the miner's death was due to pneumoconiosis and that the pneumoconiosis arose out of employment in the Nation's coal mines.

§410.454 Determining the existence of pneumoconiosis, including statutory presumption—survivor's claim.

(a) *Medical findings*. A finding of the existence of pneumoconiosis as defined in §410.110(o)(1) may be made under the provisions of §410.428 by:

(1) Chest roentgenogram; or

(2) Biopsy; or

(3) Autopsy.

(b) *Presumption relating to respiratory or pulmonary impairment—survivor's claim*. (1) Even though the existence of pneumoconiosis is not established as provided in paragraph (a) of this section, if other evidence demonstrates the existence of a chronic respiratory or pulmonary impairment from which the miner was totally disabled (see §410.412) prior to his death, it will be presumed in the absence of evidence to the contrary (see paragraph (b)(2) of this section) that the death of the miner was due to pneumoconiosis.

(2) This presumption may be rebutted only if it is established that the miner did not have pneumoconiosis, or that his respiratory or pulmonary impairment did not arise out of, or in connection with, employment in a coal mine.

(3) The provisions of this paragraph shall apply where a miner was employed for 15 or more years in one or more of the Nation's underground coal mines; in one or more of the Nation's other coal mines where the environmental conditions were substantially similar to those in an underground coal mine; or in any combination of both.

(4) However, where the evidence shows a work history reflecting many years of such coal mine employment (although less than 15) as well as a severe lung impairment, such evidence may be considered, in the exercise of sound judgment, to establish entitlement in such case: *Provided*, That a mere showing of a respiratory or pulmonary impairment shall not be sufficient to establish such entitlement.

(c) *Other relevant evidence*. Even though the existence of pneumoconiosis is not established as provided in paragraph (a) or (b) of this section, a finding of death due to pneumoconiosis may be made if other relevant evidence establishes the existence of a totally disabling chronic respiratory or pulmonary impairment, and that such impairment arose out of employment in a coal mine. As used in this paragraph, the term *other relevant evidence* includes medical tests such as blood gas studies, electrocardiogram, pulmonary function studies, or physical performance tests, and any medical history, evidence submitted by the miner's physician, his spouse's affidavits, and in the case of a deceased miner, other appropriate affidavits of persons with knowledge of the individual's physical condition, and other supportive materials. In any event, no claim for benefits under part B of title IV of the Act shall be denied solely on the basis of a negative chest roentgenogram (X-ray).

§410.456 Determining origin of pneumoconiosis, including statutory presumption—survivor's claim.

(a) If a miner was employed for 10 years or more in the Nation's coal mines, and suffered from pneumoconiosis, it will be presumed, in the absence of persuasive evidence to the contrary, that the pneumoconiosis arose out of such employment.

(b) In any other case, the claimant must submit the evidence necessary to establish that the pneumoconiosis from which the deceased miner suffered, arose out of employment in the Nation's coal mines. (See §410.110 (h), (i), (j), (k), (l), and (m).)

§410.458 Irrebuttable presumption of death due to pneumoconiosis—survivor's claim.

There is an irrebuttable presumption that the death of a miner was due to pneumoconiosis if he suffered from a chronic dust disease of the lung which meets the requirements of §410.418.

§410.462 Presumption relating to respirable disease.

(a) Even though the existence of pneumoconiosis as defined in §410.110 (o)(1) is not established as provided in §410.454(a), if a deceased miner was employed for 10 years or more in the Nation's coal mines and died from a respirable disease, it will be presumed, in the absence of evidence to the contrary, that his death was due to pneumoconiosis arising out of employment in a coal mine.

(b) Death will be found due to a respirable disease when death is medically ascribed to a chronic dust disease, or to another chronic disease of the lung. Death will not be found due to a respirable disease where the disease reported does not suggest a reasonable possibility that death was due to pneumoconiosis. Where the evidence establishes that a deceased miner suffered from pneumoconiosis or a respirable disease and death may have been due to multiple causes, death will be found due to pneumoconiosis if it is not medically feasible to distinguish which disease caused death or specifically how much each disease contributed to causing death.

§410.470 Determination by nongovernmental organization or other governmental agency.

The decision of any nongovernmental organization or any other governmental agency that an individual is, or is not, disabled for purposes of any contract, schedule, regulation, or law, or that his death was or was not due to a particular cause, shall not be determinative of the question of whether or not an individual is totally disabled due to pneumoconiosis, or was totally disabled due to pneumoconiosis. As used in this section, the term *other gov-*

ernmental agency includes the Administration with respect to a determination or decision relating to entitlement to disability insurance benefits under section 223 of the Social Security Act, since the requirements for entitlement under the latter Act differ from those relating to benefits under this part. However, a final determination or decision that an individual is disabled for purposes of section 223 of the Social Security Act where the cause of such disability is pneumoconiosis, shall be binding on the Administration on the issue of disability with respect to claims under this part.

§ 410.471 Conclusion by physician regarding miner's disability or death.

The function of deciding whether or not an individual is totally disabled due to pneumoconiosis, or was totally disabled due to pneumoconiosis at the time of his death, or that his death was due to pneumoconiosis, is the responsibility of the Administration. A statement by a physician that an individual is, or is not, *disabled, permanently disabled, totally disabled, totally and permanently disabled, unable to work,* or a statement of similar import, being a conclusion upon the ultimate issue to be decided by the Administration, shall not be determinative of the question of whether or not an individual is under a disability. However, all statements and other evidence (including statements of the miner's physician) shall be considered in adjudicating a claim. In considering statements of the miner's physician, appropriate account shall be taken of the length of time he treated the miner.

§ 410.472 Consultative examinations.

Upon reasonable notice of the time and place thereof, any individual filing a claim alleging to be totally disabled due to pneumoconiosis shall present himself for and submit to reasonable physical examinations or tests, at the expense of the Administration, by a physician or other professional or technical source designated by the Administration or the State agency authorized to make determinations as to disability. If any such individual fails or refuses to present himself for any examination or test, such failure or refusal, unless the Administration determines that there is good cause therefor, may be a basis for determining that such individual is not totally disabled. Religious or personal scruples against medical examination or test shall not excuse an individual from presenting himself for a medical examination or test. Any claimant may request that such test be performed by a physician or other professional or technical source of his choice, the reasonable expense of which shall be borne by the Administration (see § 410.240(h)). However, granting such request does not preclude the Administration from requiring that additional or supplemental tests be conducted by a physician or other professional or technical source designated by the Administration.

§ 410.473 Evidence of continuation of disability.

An individual who has been determined to be totally disabled due to pneumoconiosis, upon reasonable notice, shall, if requested to do so (e.g., where there is an issue about the validity of the original adjudication of disability) present himself for and submit to examinations or tests as provided in § 410.472, and shall submit medical reports and other evidence necessary for the purposes of determining whether such individual continues to be under a disability.

§ 410.474 Place and manner of submitting evidence.

Evidence in support of a claim for benefits based on disability shall be filed in the manner and at the place or places prescribed in subpart B of this part, or where appropriate, at the office of a State agency authorized under agreement with the Secretary to make determinations as to disability under title II of the Social Security Act, or with an employee of such State agency authorized to accept such evidence at a place other than such office.

§ 410.475 Failure to submit evidence.

An individual shall not be determined to be totally disabled unless he furnishes such medical and other evidence thereof as is reasonably required to establish his claim. Religious or personal scruples against medical examinations, tests, or treatment shall not excuse an individual from submitting evidence of disability.

§ 410.476 Responsibility to give notice of event which may affect a change in disability status.

An individual who is determined to be totally disabled due to pneumoconiosis shall notify the Administration promptly if:

(a) His respiratory or pulmonary condition improves; or

(b) He engages in any gainful work or there is an increase in the amount of such work or his earnings therefrom.

§ 410.490 Interim adjudicatory rules for certain part B claims filed by a miner before July 1, 1973, or by a survivor where the miner died before January 1, 1974.

(a) *Basis for rules.* In enacting the Black Lung Act of 1972, the Congress noted that adjudication of the large backlog of claims generated by the earlier law could not await the establishment of facilities and development of medical tests not presently available to evaluate disability due to pneumoconiosis, and that such claims must be handled under present circumstances in the light of limited medical resources and techniques. Accordingly, the Congress stated its expectancy that the Secretary would adopt such interim evidentiary rules and disability evaluation criteria as would permit prompt and vigorous processing of the large backlog of claims consistent with the language and intent of the 1972 amendments and that such rules and criteria would give full consideration to the combined employment handicap of disease and age and provide for the adjudication of claims on the basis of medical evidence other than physical performance tests when it is not feasible to provide such tests. The provisions of this section establish such interim evidentiary rules and criteria. They take full account of the congressional expectation that in many instances it is not feasible to require extensive pulmonary function testing to measure the total extent of an individual's breathing impairment, and that an impairment in the transfer of oxygen from the lung alveoli to cellular level can exist in an individual even though his chest roentgenogram (X-ray) or ventilatory function tests are normal.

(b) *Interim presumption.* With respect to a miner who files a claim for benefits before July 1, 1973, and with respect to a survivor of a miner who dies before January 1, 1974, when such survivor timely files a claim for benefits, such miner will be presumed to be totally disabled due to pneumoconiosis, or to have been totally disabled due to pneumoconiosis at the time of his death, or his death will be presumed to be due to pneumoconiosis, as the case may be, if:

(1) One of the following medical requirements is met:

(i) A chest roentgenogram (X-ray), biopsy, or autopsy establishes the existence of pneumoconiosis (see § 410.428); or

(ii) In the case of a miner employed for at least 15 years in underground or comparable coal mine employment, ventilatory studies establish the presence of a chronic respiratory or pulmonary disease (which meets the requirements for duration in § 410.412(a)(2)) as demonstrated by values which are equal to or less than the values specified in the following table:

	Equal to or less than—	
	FEV_1	MVV
67" or less	2.3	92
68"	2.4	96
69"	2.4	96
70"	2.5	100
71"	2.6	104
72"	2.6	104
73" or more	2.7	108

(2) The impairment established in accordance with paragraph (b)(1) of this section arose out of coal mine employment (see §§ 410.416 and 410.456).

(3) With respect to a miner who meets the medical requirements in paragraph (b)(1)(ii) of this section, he will be presumed to be totally disabled due to pneumoconiosis arising out of coal mine employment, or to have been totally disabled at the time of his death due to pneumoconiosis arising out of such employment, or his death will be presumed to be due to pneumoconiosis arising out of such employment, as the case may be, if he has

at least 10 years of the requisite coal mine employment.

(c) *Rebuttal of presumption*. The presumption in paragraph (b) of this section may be rebutted if:

(1) There is evidence that the individual is, in fact, doing his usual coal mine work or comparable and gainful work (see § 410.412(a)(1)), or

(2) Other evidence, including physical performance tests (where such tests are available and their administration is not contraindicated), establish that the individual is able to do his usual coal mine work or comparable and gainful work (see § 410.412(a)(1)).

(d) *Application of presumption on readjudication*. Any claim initially adjudicated under the rules in this section will, if the claim is for any reason thereafter readjudicated, be readjudicated under the same rules.

(e) *Failure of miner to qualify under presumption in paragraph (b) of this section*. Where it is not established on the basis of the presumption in paragraph (b) of this section that a miner is (or was) totally disabled due to pneumoconiosis, or was totally disabled due to pneumoconiosis at the time of his death, or that his death was due to pneumoconiosis, the claimant may nevertheless establish the requisite disability or cause of death of the miner under the rules set out in §§ 410.412 to 410.462.

APPENDIX TO SUBPART D

A miner with pneumoconiosis who meets or met one of the following sets of medical specifications, may be found to be totally disabled due to pneumoconiosis at the pertinent time, in the absence of evidence rebutting such finding:

(1) Arterial oxygen tension at rest (sitting or standing) or during exercise and simultaneously determined arterial $p^{o}{}_2$ equal to, or less than, the values specified in the following table:

Arterial $p^{co}{}_2$ (mm. Hg)	Arterial $p^{o}{}_2$ equal to or less than (mm. Hg)
30 or below	65
31	64
32	63
33	62
34	61
35	60
36	59
37	58
38	57
39	56
40 or above	55

or

(2) Cor pulmonale with right-sided congestive failure as evidenced by peripheral edema and liver enlargement, with:

(A) Right ventricular enlargement or outflow tract prominence on X-ray or fluoroscopy; or

(B) ECG showing QRS duration less than 0.12 second and R of 5 mm. or more in V_1 and R/S of 1.0 or more in V_1 and transition zone (decreasing R/S) left of V_1;

or

(3) Congestive heart failure with signs of vascular congestion such as hepatomegaly or peripheral or pulmonary edema, with:

(A) Cardio-thoracic ratio of 55 percent or greater, or equivalent enlargement of the transverse diameter of the heart, as shown on teleroentgenogram (6-foot film); or

(B) Extension of the cardiac shadow (left ventricle) to the vertebral column on lateral chest roentgenogram and total of S in V_1 or V_2 and R in V_5 or V_6 of 35 mm. or more on ECG.

Subpart E—Payment of Benefits

AUTHORITY: Secs. 411(a), 412 (a) and (b), 413(b), 426(a), and 508, 83 Stat. 793; 30 U.S.C. 921(a), 922 (a) and (b), 923(b), 936(a), and 957; sec. 410.565 also issued under sec. 3, 80 Stat. 309, 31 U.S.C. 952, unless otherwise noted.

SOURCE: 36 FR 23758, Dec. 14, 1971, unless otherwise noted.

§ 410.501 Payment periods.

Benefits are paid to beneficiaries during entitlement for payment periods consisting of full calendar months.

§ 410.505 Payees.

(a) *General*. Benefits may be paid as appropriate, to a beneficiary (see § 410.110(r)), to a qualified dependent (see § 410.511), or to a representative payee on behalf of a beneficiary or dependent (see § 410.581ff). Also where an amount is payable under part B of title IV of the Act for any month to two or more individuals who are members of the same family, the Social Security Administration may, in its discretion, certify to any two or more of such individuals joint payment of the total benefits payable to them for such month.

(b) *Joint payee dies before cashing check*. Where a check has been issued for joint payment to an individual and spouse residing in the same household and one of them dies before the check is cashed, the Social Security Administration may give the survivor permission to cash the check. The permission is carried out by stamping the face of the check. An official of the Social Security Administration or the Treasury Disbursing Office must sign and name the survivor as the payee of the check (see 31 CFR 360.8). Where the uncashed check is for benefits for a month after the month of death, authority to cash the check will not be given to the surviving payee unless the funds are needed to meet the ordinary and necessary living expenses of the surviving payee.

(c) *Adjustment or recovery of overpayment*. Where a check representing payment of benefits to an individual and spouse residing in the same household is negotiated by the surviving payee in accordance with the authorization in paragraph (b) of this section and where the amount of the check exceeds the amount to which the surviving payee is entitled, appropriate adjustment or recovery with respect to such excess amount shall be made in accordance with section 204(a) of the Act (see subpart F of part 404).

[43 FR 34780, Aug. 7, 1978]

§ 410.510 Computation of benefits.

(a) *Basic rate*. The benefit amount of each beneficiary entitled to a benefit for a month is determined, in the first instance, by computing the "basic rate." The basic rate is equal to 50 percent of the minimum monthly payment to which a totally disabled Federal employee in Grade GS-2 would be entitled for such month under the Federal Employees' Compensation Act, chapter 81, title 5 U.S.C. That rate for a month is determined by:

(1) Ascertaining the lowest annual rate of pay ("step 1") for Grade GS-2 of the General Schedule applicable to such month (see 5 U.S.C. 5332);

(2) Ascertaining the monthly rate thereof by dividing the amount determined in paragraph (a)(1) of this section by 12;

(3) Ascertaining the minimum monthly payment under the Federal Employees' Compensation Act by mu tiplying the amount determined i paragraph (a)(2) of this section by 0.7 (that is, by 75 percent) (see 5 U.S.(8112); and

(4) Ascertaining the basic rate unde the Act by multiplying the amount de termined in paragraph (a)(3) of this sec tion by 0.50 (that is, by 50 percent).

(b) *Basic benefit*. When a miner o widow is entitled to benefits for month for which he or she has no de pendents who qualify under subpart (of this part, and when a surviving chil of a miner or widow, or a parent, broth er, or sister of a miner, is entitled t benefits for a month for which he o she is the only beneficiary entitled t benefits, the amount of benefits t which such beneficiary is entitled i equal to the basic rate as computed i accordance with this section (raised, i not a multiple of 10 cents, to the nex higher multiple of 10 cents (see para graph (d) of this section)). This amoun is referred to as the *basic benefit*.

(c) *Augmented benefit*. (1) When a miner or widow is entitled to benefit for a month for which he or she has one or more dependents who qualify unde subpart C of this part, the amount o benefits to which such miner or widow is entitled is increased. This increase i referred to as an *augmentation*.

(2) Any request to the Administra tion that the benefits of a miner or widow be augmented in accordance with this paragraph shall be in writing on such form and in accordance with such instructions as are prescribed by the Administration. Such request shall be filed with the Administration in accordance with those provisions of subpart B of this part dealing with the filing of claims as if such request were a claim for benefits, and as if such dependent were the *beneficiary* referred to therein. (See § 410.220(f).) Ordinarily, such request is made as part of the claim of the miner or widow for benefits.

(3) The benefits of a miner or widow are augmented to take account of a particular dependent beginning with the first month in which such dependent satisfies the conditions set forth in subpart C of this part, and continues to be augmented through the month before the month in which such depend-

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existing roentgenographic units acquired by the examining facility prior to July 27, 1973, shall have a minimum rating of 200 mA at 100 kVp; (b) generators of units acquired subsequent to that date shall have a minimum rating of 300 mA at 125 kVp.

Note.—A generator with a rating of 150 kVp is recommended.

(5) Roentgenograms made with battery-powered mobile or portable equipment shall be made with units having a minimum rating of 100 mA at 110 kVp at 500 Hz, or 200 mA at 110 kVp at 60 Hz.

(6) Capacitor discharge, and field emission units may be used.

(7) Roentgenograms shall be given only with equipment having a beam-limiting device which does not cause large unexposed boundaries. The use of such a device shall be discernible from an examination of the roentgenogram.

(8) To insure high quality chest roentgenograms:

(i) The maximum exposure time shall not exceed 1/20 of a second except that with single phase units with a rating less than 300 mA at 125 kVp and subjects with chest over 28 cm postero-anterior, the exposure may be increased to not more than 1/10 of a second;

(ii) The source or focal spot to film distance shall be at least 6 feet;

(iii) Only medium-speed film and medium-speed intensifying screens shall be used;

(iv) Film-screen contact shall be maintained and verified at 6-month or shorter intervals;

(v) Intensifying screens shall be inspected at least once a month and cleaned when necessary by the method recommended by the manufacturer;

(vi) All intensifying screens in a cassette shall be of the same type and made by the same manufacturer;

(vii) When using over 90 kV, a suitable grid or other means of reducing scattered radiation shall be used;

(viii) The geometry of the radiographic system shall insure that the central axis (ray) of the primary beam is perpendicular to the plane of the film surface and impinges on the center of the film.

(9) Radiographic processing:

(i) Either automatic or manual film processing is acceptable. A constant time-temperature technique shall be meticulously employed for manual processing.

(ii) If mineral or other impurities in the processing water introduce difficulty in obtaining a high-quality roentgenogram, a suitable filter or purification system shall be used.

(10) Before the miner is advised that the examination is concluded, the roentgenogram shall be processed and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard roentgenogram, another shall be made immediately.

(11) An electric power supply shall be used which complies with the voltage, current, and regulation specified by the manufacturer of the machine.

(12) A densitometric test object may be required on each roentgenogram for an objective evaluation of film quality at the discretion of the Department of Labor.

(13) Each roentgenogram made hereunder shall be permanently and legibly marked with the name and address of the facility at which it is made, the miner's DOL claim number, the date of the roentgenogram, and left and right side of film. No other identifying markings shall be recorded on the roentgenogram.

Comments received: (a) Several commenters express strong endorsement of the contents of this Apendix. One comment suggests that the Department review the standards of Appendix A with a physician or X-ray technician to determine whether they are reasonable to those individuals in field facilities. (b) One comment takes issue with paragraph 6, which states that field emission units may be used. According to this commenter, these devices operate at very high kilovoltage (350 kVp), and calcifications are thereby obliterated. (c) Another commenter urges that the last sentence of paragraph 10 be deleted as it is useless and confusing. The commenter points out that the original intent of such a requirement was to protect the confidentiality of the miner. Such protection, it is said, is not a concern in the case of a miner who has a chest X-ray taken in connection with a claim for black lung benefits. (d) Two commenters recommend that paragraph 14 be dropped from the Appendix. They state that there is no significant risk to the miner when a well-columnated unit is used.

Discussion and changes: (a) The Department has reviewed the standards contained in Appendix A with physicians and X-ray technicians and it has been determined that the standards are reasonable and usable in field facilities. (b) Although field emission units may obliterate calcifications, they enhance the recording of soft tissue and opacities. Since the latter are particularly relevant in diagnosing coal workers' pneumoconiosis, the advantages of field emission units in the black lung claims process outweigh the disadvantages. (c) The Department agrees with the comment concerning the last sentence in section 10 and that sentence has been deleted. (d) The Department agrees with the comments concerning paragraph 14 and that paragraph has been deleted.

Appendix B—Standards for Administration and Interpretation of Ventilatory Function Tests

The following standards are established in accordance with section 402(f)(1)(D) of the Act. They were developed in consultation with the National Institute for Occupational Safety and Health (NIOSH). These standards are promulgated for the guidance of physicians and medical technicians to insure that uniform procedures are used in administering and interpreting ventilatory function tests and that the best available medical evidence will be submitted in support of a claim for black lung benefits. If it is established that one or more standards have not been met, the claims adjudicator may consider such fact in determining the evidentiary weight to be given to the results of the ventilatory function tests.

(1) Instruments to be used for the administration of pulmonary function tests shall be approved by NIOSH and shall conform to the following criteria:

(i) The instrument shall be accurate within ±50 ml or within ±3 percent of reading, whichever is greater.

(ii) The instrument shall be capable of measuring vital capacity from 0 to 7 liters BTPS.

(iii) The instrument shall have a low inertia and offer low resistance to airflow such that the resistance to airflow at 12 liters per second must be less than 1.5 cm H_2O/liter/sec.

(iv) The zero time point for the purpose of timing the FEV, shall be determined by extrapolating the steepest portion of the volume-time curve back to the maximal inspiration volume or by an equivalent method.

(v) Instruments incorporating measurements of airflow to determine volume shall conform to the same volume accuracy stated in subparagraph (1)(i) of this Appendix B when presented with flow rates from at least 0 to 12 liters per second.

(vi) The instrument or user of the instrument must have a means of correcting volumes to body temperature saturated with water vapor (BTPS) under conditions of varying ambient spirometer temperatures and barometric pressures.

(vii) The instrument used shall provide a tracing of either flow versus volume or volume versus time during the entire forced expiration and volume versus time during the MVV maneuver. A tracing is necessary to determine whether the patient has performed the test properly. The tracing must be of sufficient size that hand measurements may be made within the requirement of subparagraph (1)(i) of this Appendix B. If a paper record is made it must have a paper speed of at least 2 cm/sec and a volume sensitivity of at least 10.0 mm of chart per liter of volume. The recorder tracing must display the entire FVC maneuver at a constant speed for at least 10 seconds after the onset of exhalation. This constant speed must be reached prior to the onset of exhalation.

(viii) The instrument shall be capable of accumulating volume for a minimum of 10 seconds after the onset of exhalation.

(ix) The forced expiratory volume in 1 sec (FEV_1) measurement shall comply with the accuracy requirements stated in subparagraph (1)(i) of this Appendix B. That is, they shall be accurately measured to within ±50 ml or with ±3 percent of reading, whichever is greater.

(x) The instrument must be capable of being calibrated in the field with respect to the FEV_1. This calibration of the FEV_1 may be done either directly or indirectly through volume and time base measurements. The volume calibration source shall provide a volume displacement of at least 3 liters and shall be accurate to within ±30 ml.

(xi) For measuring maximum voluntary ventilation (MVV) the instrument shall have a response which is flat within ±10 percent up to 4 Hz at flow rates up to 12 liters per second over the volume range. The time for exhaled volume integration or recording shall be no less than 12 sec. and no more than 15 sec. The indicated time shall be accurate to within ±3 percent.

A recording of the spirometer tracing is required, and the volume sensitivity shall be such that 10 mm or more deflection corresponds to 1 liter volume.

(2) The administration of pulmonary function tests shall conform to the following criteria:

(i) Tests shall not be performed during or soon after an acute respiratory illness.

(ii) For the FEV_1 and FVC, use of a nose clip is required. The procedures shall be explained in simple terms to the patient who shall be instructed to loosen any tight clothing and stand in front of the apparatus. The subject may sit, or stand, but care should be taken on repeat testing that the same position be used. Particular attention shall be given to insure that the chin is slightly elevated with the neck slightly extended. The patient shall be instructed to make a full inspiration, either from the spirometer or the open atmosphere, using a normal breathing pattern and then blow into the apparatus, without interruption, as hard, fast, and completely as possible. At least three forced expirations shall be carried out. During the maneuvers, the patient shall be observed for compliance with instructions. The expirations shall be checked visually for reproducibility from the flow-volume or volume-time tracings. The effort shall be judged unacceptable when the patient:

(A) Has not reached full inspiration preceding the forced expiration; or

(B) Has not used maximal effort during the entire forced expiration; or

(C) Has not continued the expiration for least 5 sec. or until an obvious plateau in the volume-time curve has occurred; or

(D) Has coughed or closed his glottis; or

(E) Has an obstructed mouthpiece or a leak around the mouthpiece (obstruction due to tongue being placed in front of mouthpiece, false teeth falling in front of mouthpiece, etc.); or

(F) Has an unsatisfactory start of expiration, one characterized by excessive hesitation (or false starts), and therefore not allowing back extrapolation of time 0 (extrapolated volume on the volume-time tracing must be less than 10 percent of the FVC); or

(G) Has an excessive variability between the three acceptable curves. The variation between the two largest FEV_1's of the three acceptable tracings should not exceed 5 percent of the largest FEV_1 or 100 ml, whichever is greater.

(iii) For the MVV, the subject shall be instructed before beginning the test that he or she will be asked to breathe as deeply and as rapidly as possible for approximately 15 seconds.

The test shall be performed with the subject in the standing position, if possible. Care shall be taken on repeat testing that the same position be used. The subject shall breathe normally into the mouthpiece of the apparatus for 10 to 15 seconds to become accustomed to the system. The subject shall then be instructed to breathe as deeply and as rapidly as possible, and shall be continually encouraged during the remainder of the maneuver. Subject shall continue the maneuver for 15 seconds. At least 5 minutes of rest shall be allowed between maneuvers. At least three MVV's shall be carried out. (But see § 718.103(b).) During the maneuvers the patient shall be observed for compliance with instructions. The effort shall be judged unacceptable when the patient:

(A) Has not maintained consistent effort for at least 12 to 15 seconds; or

(B) Has coughed or closed his glottis; or

(C) Has an obstructed mouthpiece or a leak around the mouthpiece (obstruction due to tongue being placed in front of mouthpiece, false teeth falling in front of mouthpiece, etc.); or

(D) Has an excessive variability between the three acceptable curves. The variation between the two largest MVV's of the three satisfactory tracings shall not exceed 10 percent.

(iv) A calibration check shall be performed on the instrument each day before use, using a volume source of at least three liters, accurate to within ±1 percent of full scale. The room air in the syringe is introduced into the spirometer once with a flow rate of approximately 0.5 liters per second (six seconds emptying time with a 3-liter syringe) and once with a higher flow rate of approximately 3.0 liters per second (one second emptying time with a 3-liter syringe). The volume measured by the spirometer shall be between 2.90 and 3.10 liters for both trials. Accuracy of the time measurement used in determining the FEV_1 shall be checked using the manufacturer's stated procedure and shall be within ±3 percent of actual. The procedure described herein shall be performed as well as any other procedures suggested by the manufacturer of the spirometer being used.

(v)(A) The first step in evaluating a spirogram for the FEV_1 shall be to determine whether or not the patient has performed the test properly or as described in (2)(ii) above. From the three satisfactory tracings, the forced expiratory volume in one second (FEV_1) shall be measured and recorded. The largest observed FEV_1 shall be used in the analysis, corrected to BPTS.

(B) Only MVV maneuvers which demonstrate consistent effort for at least 12 seconds shall be considered acceptable. The largest accumulated volume for a 12 second period corrected to BPTS and multiplied by five is to be reported as the MVV.

Comments received: (a) Testimony was received which approved of the criteria for spirometer performance and the requirements for measurement of tracings. One person comments that the regulations contain excessively meticulous detail in instrument design and calibration. One comment presents an alternative standard for spirometric equipment which is based upon a statement from the American College of Chest Physicians. One commenter states that NIOSH would probably want to avoid the responsibility and costliness of developing and operating a full-time testing facility. He states that certified documentation showing conformity to criteria should be provided for approval by NIOSH. (b) One comment suggests that NIOSH procedures for approval of instruments should be specified, and that paragraph (1)(i) be amended to require accuracy within ±5 percent of reading in view of the permitted 10 percent variation between tracings and in the interest of the cost of equipment and testing. Another comment suggests that paragraph (1)(i) be reworded to provide that the instrument be accurate within ±50 ml or within ±3 percent of static volume, whichever is greater. (c) Another comment suggests that the term "low inertia" in paragraph (1)(iii) be defined and that the phrase "resistance to air flow" in the same paragraph should define the point of pressure pick-up in terms of distance from the subject's mouth. (d) The same comment states, in regard to paragraph (1)(vii), that a sensitivity of 10.0 mm/liter is too small to enable satisfactory discrimination of tracing against a chart grid or rule scale. (e) Another commenter suggests that paragraph (1)(viii) be rewritten by someone with a medical background in pulmonary function testing or according to the standards set by the American Thoracic Society. (f) One commenter suggests that paragraph (1)(ix) be reworded to read that the FEV_1 shall comply with the accuracy requirements of ±100 ml/second, or ±5 percent, whichever is greater. (g) This same person recommends that paragraph (1)(x) provide that the instrument be capable of being calibrated in the field with respect to the FEV_1, through simultaneous volume and time based measurements, and that the calibration be accurate within ±50 ml, or within ±3 percent of the reading, having a total volume displacement of at least three liters and a time constant of one, or an FEV_1 to FVC ratio of not less than 65 percent. (h) One commenter states that paragraph (1)(x) which indicates that the instrument must be capable of being calibrated in the field with respect to FEV_1 would require a volume displacement device which can deliver the calibrated volume within an exactly prescribed short time interval. The commenter states that no such portable device exists. (i) Regarding paragraph (1)(xi), two commenters suggest that this section be revised to provide that, for measuring MVV, the instrument must have a response which is flat within ±5 percent, using a sine wave at 250 liters per minute, generated by a stroke of two liters, using frequencies up to approximately two cycles per second. Another person suggests that this paragraph be rewritten so that 4Hz becomes 8Hz. One commenter objects to the term "Hertz," because it is, by definition, an electrical expression. (j) One comment states that paragraph (2)(ii) seems to describe a "closed" spirometry system, while 90 percent of the tests performed use an "open" spirometry system. It suggests that this paragraph be modified to avoid a misinterpretation of a preference for a particular spirometry system. One commenter also states that to be consistent with paragraph (1)(iv), the alternative should specifically permit either method of recording the maneuver for the FEV_1. Another comment recommends that the provision of paragraph (2)(ii) prescribing full inspiration from a normal breathing pattern should be amended to provide that this be from the open atmosphere following normal resting breathing. This comment notes that open-circuit FVC/FEV_1 testing predominates in international and industrial examinations on practical and hygienic grounds. (k) One comment states that the requirement of paragraph G is too lax, and that all three measurements, or, if more than three were made, the three largest, should meet these criteria. (l) In regard to paragraph (2)(iii), one person would reword the first paragraph, subpart (a), and paragraph (2)(v)(B) to state that the subject should continue the maneuver for ten to fifteen seconds. (m) On the calibration provision of paragraph (2)(iv), one comment states that the latest calibration method of the American Thoracic Society calls for a three-liter volume source and two speeds of two-second (normal) and six second (obstructed) injections per three liters of volume, and that these are more realistic to prevent artifacts than the speeds prescribed. (n) One comment would strike the provision of paragraph (2)(v)(B) calling for the MVV value to be multiplied by five.

Discussion and changes: (a) The requirements of this Appendix for the administration of ventilatory tests are for the guidance of physicians and medical technicians to insure that uniform procedures are used in the administration and interpretation of ventilatory function studies and also to insure that the best available medical evidence will be submitted in connection with a claim for black lung benefits. The criteria contained in this Appendix were developed by the American Thoracic Society (ATS) and the National Institute for Occupational Safety and Health (NIOSH), and are taken from the Report of the Snowbird Workshop on Standardization of Spirometry. (See *American Review of Respiratory Disease*, vol. 119 (1979) at Pp. 831–838.) The Snowbird Workshop had representation from both clinical and epidemiological areas of interest, and the report represents a consensus of the minimum requirements for ventilatory testing. NIOSH has reviewed the standards proposed by the commenter and has found them to be, in general, much less stringent. The Department has chosen to use the recommendations from the Snowbird Workshop for the following reasons: (1) There were more than 25 participants at the American Thoracic Society's Snowbird Workshop, representing a range of professional backgrounds. The American College of Chest Physician's committee had only nine members; (2) the American Thoracic Society's recommended standard was presented at the May 1977 annual ATS meeting and published in the August 1977 ATS News. During the period since May 1977, the ATS recommended standards have been open for comment. It has only been very recently that any objections have been raised concerning the ATS recommended standards, (3) the ACCP standard was only recently published; (4) each of the ATS statements which concern equipment requirements is followed by a rationale which most often is based on actual data and not merely opinion, and (5) while there are a few spirometers which will not meet these equipment requirements NIOSH's preliminary spirometer testing results indicate that many spirometers will meet these requirements, and at least two are "office" type spirometers costing less than $1,000.00. The most equitable method of determining if spirometers meet the requirements is to test all spirometers using the same testing protocol. The NIOSH testing protocol will be available for spirometer manufacturers' input and comment before it is implemented. Having each manufacturer submit documentation would place an undue hardship on the spirometer manufacturers and would be difficult to administer. NIOSH's experience with the testing of spirometers indicates that the testing protocol would require very little testing effort and would be simple to administer. NIOSH currently has available advance spirometer testing equipment which has been previously used in research programs and is suitable for routine spirometer testing. (b) The Department has reduced the acceptable variability between tracings from the FEV_1 from 10 percent to 5 percent in conformance with the recent recommendations of the ATS. The accuracy requirement of 3 percent is based on the ATS recommended requirement of 3 percent. This requirement is based on data which indicate that the within-subject biological variability of repeated measurements of the FEV_1 is approximately 3 percent. NIOSH's preliminary testings of spirometers indicate that a majority of spirometers currently manufactured will meet the 3 percent accuracy requirement. The standard uses FVC instead of static volume since FVC is the measurement of interest. (c) Inertia is defined in the resistance requirement of (1)(iii); that is, higher inertia will produce a higher resistance measurement at 12 liters per second with a simulated FVC maneuver. The minor details of resistance measurement will be covered in the NIOSH spirometery testing protocol. It should be obvious that the pressure pick up point for measurement of resistance would be at the mouthpiece or the point at which the patient is attached to the instrument. (d) The tracing sensitivity requirement is derived from the report of the ATS Snowbird Workshop. This requirement is only the minimum sensitivity necessary and the Department urges that a more sensitive recorder be used when possible. (e) The ATS has recently revised its standard in this area and (1)(viii) has been changed accordingly. (f) The FEV_1 accuracy requirement is identical to the recommendation of the ATS Snowbird Workshop. The ATS 3 percent accuracy requirement is based on actual data and the biological variability of the FEV_1 (which is approximately ½ of the FEV 25–75 percent). (g) The Department agrees that calibration of the spirometer before each day's use is important. For this reason the Department has also recommended the ATS 3-liter calibrating syringe procedure. Any calibrating source should be at least 3 times more accurate than the accuracy of the device being calibrated. Therefore, the 3-liter calibrating syringe should be accurate to within ±30 ml or 1 percent of full scale volume. The calibrating device described by the commenter is only manufactured by the commenter's company. It would be impractical to require this device's use. (h) The time measurement used in determining FEV_1 can be checked with a stop watch and careful monitoring of the chart speed, thereby verifying the tracing time base accuracy. In addition, large syringes with simultaneous measurement of the time taken to empty a predetermined volume into a spirometer are now available. These techniques are capable of being employed in the field. (i) The requirements of this subpart are in accordance with the recommendations contained in the Snowbird Workshop, and the frequency response requirement of that Workshop has been actually lowered from eight to four Hertz, upon the advice of NIOSH. The requirement for a higher frequency response has been demonstrated by research studies which are referenced in the ATS recommended standard. In general, the high frequency response test is needed to detect those spirometers with an unacceptable amount of overshoot. However, aside from the two cycle suggestion, NIOSH is seriously considering the recommendations of the first two commenters, and if in the future NIOSH recommends the use of the MVV testing symbol described, the regulation will be amended. "Hertz" is defined in Webster's New World Dictionary as "the international unit of frequency, equal to one cycle per second." Since the regulation refers to frequency, the unit "Hertz" is entirely appropriate. (j) Either an "open" or "closed" spirometry system is acceptable and the wording of the regulation has been changed to so indicate. (k) The original recommendations of the American Thoracic Society's Snowbird Workshop was "the two best of three acceptable curves should not vary by more than 10 percent of reading, or 100 ml, whichever is greater." The Department of Labor criteria were identical to the ATS's original recommendations. Very recently, however, the ATS has modified its recommendations to read "the two best of the three acceptable curves should not vary by more than ±5 percent of reading or ±100 ml, whichever is greater." The regulation has been changed to conform with the latest ATS recommendation. The regulatory requirements are still less stringent than those proposed by the commenter as the Department does not believe that the requirements should be more stringent than those proposed by the Snowbird Workshop. (l) The wording of subparagraph (1)(xi) implies a 12 to 15 second period. Therefore, subparagraph (2)(iii)(A) has been changed accordingly. (m) The Department agrees with the recommendation of this commenter and (2)(iv) has been changed accordingly. (n) The unit of measurement for the MVV is liters per minute. In order to calculate liters per minute from a 12 second sample, the reported figure must be multiplied by five. Therefore, no change is necessary.

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